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Do chronically depressed individuals exhibit a hostile-submissive interpersonal style  
and what is the process of change in Cognitive Behavioural Analysis System of  
Psychotherapy?

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Doctorate in Clinical Psychology  
The University of Edinburgh  
2016

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## 1. Thesis Abstract

Cognitive Behavioural Analysis System of Psychotherapy (CBASP) has been developed to treat individuals suffering from chronic depression. There is a growing evidence base to suggest that CBASP is effective for these individuals. Given these findings, it is important to understand the process of change during CBASP and how it is affected by the components of the therapy.

**Purpose:** A systematic review and meta analysis aimed to establish whether there is evidence for one of the theoretical foundations of CBASP; that a hostile-submissive interpersonal style is associated with major depressive disorder, and in particular with chronic forms of depression, as suggested by McCullough (2000). An empirical study then aimed to investigate whether the components of CBASP are associated with symptom change for chronically depressed individuals during therapy. It also sought to examine whether individuals experienced change differently in CBASP if it was delivered without using Disciplined Personal Involvement (DPI) by the therapist. The aim of this research was to investigate the process of change within the context of CBASP for individuals receiving the therapy, and to evaluate the usefulness of a multilevel modelling approach to analysing single-case data.

**Methods:** The literature was systematically searched for research reporting a relationship between depression and interpersonal hostility and/or submissiveness and a meta-analysis conducted to test the strength of this relationship. An empirical study presents analyses of two datasets. The first is a multilevel modelling analysis of data from a CBASP case series, seeking to determine what role the components of CBASP have in symptom change during therapy. A single-case, multiple baseline study then examined the process of symptom change during CBASP. This study included individuals experiencing chronic depression, who completed a series of baseline observations followed by up to 20 sessions of CBASP over a six-month period. Participants were assigned to either receive manualised CBASP, or a form of CBASP without the interpersonal focus. The latter study employed mixed models to evaluate change in individuals in CBASP, and sought to evaluate this novel approach to single-case analysis.

**Results.** The meta analytic review provided preliminary support for McCullough's (2000) hypothesis that chronically depressed individuals tend to present as more hostile and submissive than individuals with first-episode MDD. Findings from the empirical study suggest that acquisition learning in relation to the situational analysis exercise in CBASP is associated with symptom change but not learning in relation to the interpersonal discrimination exercise. Findings from the single-case analysis, however, provided limited evidence that CBASP without the interpersonal focus is associated with less change over the first few sessions of therapy than CBASP. Multilevel modeling analysis of single cases appeared to provide a useful approach to evaluating within-individual change in therapy, compared with traditional methods such as clinically significant change indices.

**Discussion:** The findings of this thesis provide preliminary evidence for components of McCullough's (2000) CBASP model. The review's results pointed to a need for more methodologically sound studies to further investigate the role of interpersonal style in the aetiology and maintenance of chronic depression. Analyses in the empirical study appeared to support the use of Situational Analysis in bringing about symptom change in therapy, but findings were mixed in relation to the interpersonal components of CBASP. The use of a small-N design with multiple baselines allowed for a preliminary analysis of the role of DPI, but incomplete data limited this analysis to the first half of therapy.



## 2. Lay Summary of Thesis

**Introduction.** The research in this thesis sought to investigate the process of psychological change for individuals suffering from chronic depression who receive the Cognitive Analysis System of Psychotherapy (CBASP). CBASP was developed based on a theory that describes chronic depression as happening when, as a result of early negative experiences, an individual assumes that everybody has the same intentions as those significant others who previously mistreated them.

**Aims and methods.** This thesis aimed first to establish whether there is evidence in the current research literature that depressed individuals tend to come across as hostile and submissive, as is predicted by the CBASP model, and in particular whether there is evidence that this is the case for chronic depression more than single-episode major depression. A second study then presents analyses from two studies that aimed to determine whether the techniques used in CBASP are associated with improvements in symptoms during therapy for chronic depression.

**Main findings.** The findings in the thesis give some support to the CBASP model. The first study found that chronic depression tends to be associated with hostile and submissive behaviours, and that this association seems to be stronger than in major depression. The second study found evidence that the main part of CBASP, Situational Analysis, is associated with symptom improvements when individuals begin to learn from the exercise. This study also found that individuals who receive CBASP tend to experience change differently from one-another, but that it appears to be useful for people regardless of their symptom levels at the beginning of treatment. One of the aims of the thesis was to test whether statistical modelling is useful for evaluating the process of change in therapy for individual participants. The analyses found some advantages of using this approach.

**Conclusions.** Overall, the findings in this thesis give some support to the CBASP model, and provide an indication that the techniques used in CBASP are in fact associated with change. This is potentially important as it is the first study to explicitly look at whether CBASP is doing what it claims to be. However the results point to a need for more research into the risk factors for chronic depression as the review found a limited amount of existing research. The results of the empirical study also need further research to evaluate the process of change in CBASP.

### 3. Chapter 1: Systematic review and Meta-Analysis

Interpersonal styles in major and chronic depression: A systematic review and meta analysis

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### 3.1. Abstract

**Background.** McCullough's (2000) theory of chronic depression posits that a hostile-submissive interpersonal style is a characteristic that distinguishes chronically depressed individuals from those with Major Depression (MDD). This study sought to determine to what extent hostility and submissiveness feature in MDD, and whether there is evidence for a stronger effect in chronic depression.

**Methods.** A systematic literature search was conducted for research measuring the relationship between depression and hostility and/or submissiveness. A meta-analysis was carried out to determine the strength of the relationship. Separate analyses were conducted for the effects of hostility, submissiveness, and hostile-submissiveness. Subgroup analyses were performed comparing the effect sizes of chronic depression and MDD.

**Results.** Twelve studies met criteria for inclusion. Subgroup analyses revealed large effect sizes for submissiveness ( $d = 0.86$ ) and hostile-submissiveness ( $d = 0.93$ ) in chronic depression, and a medium effect for hostility ( $d = 0.72$ ). MDD was associated with medium effects for hostility ( $d = 0.58$ ) and hostile-submissiveness ( $d = 0.63$ ), and a small effect for submissiveness ( $d = 0.40$ ).

**Limitations.** The review yielded a relatively small number of papers, particularly in relation to chronic depression. The majority of included studies reported secondary analyses using baseline samples of intervention trials, with normative data as controls. Quality scores were generally low, and analyses revealed high heterogeneity, which may indicate differences between clinical populations studied.

**Conclusions.** The review provides preliminary evidence that individuals with chronic depression are more hostile-submissive than those with MDD. Results highlight the limited amount of research into the interpersonal correlates of chronic depression.

**Keywords:** CBASP; Chronic Depression; Interpersonal style; Meta-Analysis

### **3.2. Introduction**

Around one fifth of those meeting diagnostic criteria for Major Depressive Disorder (MDD) will experience episodes lasting two years or more without remission (Keller et al., 1992). In addition, a high proportion of those experiencing MDD experience at least one subsequent episode (Lavori, Dawson, & Mueller, 1994; Pincus & Pettit, 2001; Williams et al., 1997). Chronic depression, where depressive symptoms are present for two or more years, is associated with greater psychosocial and occupational impairment than acute forms of depression, including time spent off work, unemployment, use of health services, lower socio-economic status, and marital breakdown (Swan & Hull, 2007; Wells, Burnam, Rogers, Hays, & Camp, 1992). Despite the prevalence and consequences of chronic depression, it remains relatively under-researched and poorly understood (Constantino et al., 2008). Given the poor outcomes associated with this disorder, understanding its aetiology and maintenance factors would provide important insights for designing treatments for chronically depressed individuals. This paper sought to establish the current evidence for a recent model of chronic depression put forth by McCullough (2000, 2006), where individuals with chronic depression are described as having an excessively submissive and hostile interpersonal style, which acts to maintain depression by depriving individuals of meaningful interpersonal experiences. This review aims to establish to what extent the current literature supports this hypothesis.

Interpersonal functioning has been found to be a key feature in both causing and maintaining MDD. Factors such as insecure attachment, submissiveness, dependency, and interpersonal skill deficits have all been found to feature (Bifulco, Moran, Ball, & Bernazzani, 2002; Constantino et al., 2008; Coyne, 1976; Joiner,

2002). McCullough (2000) hypothesised that although these factors feature in acute depression, they manifest as more stable and severe in chronically depressed individuals. The model describes chronic depression as being associated with a preoperational level of interpersonal thinking. Two forms of chronic depression are described: early onset and late onset. In early onset, arrested maturational development is brought on by the early experience of maltreatment, loss of a significant other, or experience of neglect (Swan & Hull, 2007). Those with late onset chronic depression (age 21 and over) are thought to experience depression following a stressor. It is the prolonged experience of depression in these individuals that leads to feelings of helplessness and hopelessness, leading to preoperational thinking (e.g. 'things will never get better'). Individuals functioning at Piaget's preoperational level would then experience difficulty in assessing the interpersonal consequences of their own behaviour and in discriminating between previous maltreating significant others and current or future relationships. There is limited evidence that chronically depressed individuals can be distinguished from episodically depressed individuals on a measure of preoperational thinking (Kühnen et al., 2011), though this comes from a preliminary validation study with a relatively small sample. Chronically depressed individuals therefore would display both hostile detachment and excessive submissiveness (Constantino et al., 2008; McCullough, 2000; Swan & Hull, 2007).

There is already evidence that insecure attachment styles are associated with depressive symptoms (Besser & Priel, 2003; Oliver & Whiffen, 2003; Roberts, Gotlib, & Kassel, 1996; Wei, Mallinckrodt, Russell, & Abraham, 2004). For example, avoidant attachment in men has been found to make them vulnerable to depression (Oliver & Whiffen, 2003). Similarly, anxious attachments have been found to be

associated with perfectionism, which then increases vulnerability to depression (Wei et al., 2004). Insecure attachment has been found to operationalise into two dimensions, with both being found to be positively associated with depression (Brennan, Clark, & Shaver, 1998). These dimensions are 'anxiety', which is associated with fear of abandonment; and 'avoidance' (Brennan et al., 1998). Both have been found to be significantly associated with depression, and there is also evidence that those with high levels of attachment avoidance have low response rates to Interpersonal Psychotherapy (IPT) compared with to Cognitive Behaviour Therapy (CBT) (McBride, Atkinson, Quilty, & Bagby, 2006). Similarly, Reis and Grenyer (2004) found that fearful-avoidant attachment was associated with significantly more negative outcomes after a course of psychotherapy, and particularly over the initial sessions. The extant literature therefore suggests that attachment style is associated with depression, and with engagement in treatment, though the claims in the CBASP model may be conceptually different, as they suggest an association between depressive functioning and a developmental delay rather than attachment style alone. An avoidant style, characterised by distrust of others and a fear of rejection, has been found to be particularly important. There is also some evidence that attachment style may play a role in the likelihood of recurrence in depression. For example a study exploring the attachment patterns of women with dysthymia found that a preoccupied attachment was associated with the diagnosis (West & George, 2002), suggesting that these individuals experience low levels of agency.

Treating chronic depression poses a significant challenge. Psychological therapies developed for MDD have been found to be of limited effectiveness for this patient group. In a recent meta-analysis the overall effectiveness of psychological

therapies for chronic depression was found to represent a small effect, and also compared unfavourably with pharmacotherapy (Cuijpers et al., 2010). However the current evidence base is limited. In non meta-analytic reviews IPT, CBT, and CBASP have been found to lead to symptom improvements in individuals with chronic depression, but no studies have yet compared the models against each other (Arnow & Constantino, 2003), and there is evidence that CBT and IPT are limited for this population (Agosti & Ocepek-Welikson, 1997; Markowitz, Kocsis, Bleiberg, Christos, & Sacks, 2005). CBASP is the only therapy of the three that has been developed specifically for chronic depression. It has been the focus of several randomised controlled trials, including a large, multicentre study that found CBASP to be as effective as medication for this client group, and most effective when delivered in combination (Keller et al., 2000). Several smaller randomised controlled trials and a case series have found similar results. However the evidence base remains small and is limited to studies comparing CBASP with either no treatment or with medication.

Understanding the psychological and interpersonal correlates of chronic depression is particularly important given the limited effectiveness of current treatments. Currently CBASP appears to be the most promising psychological therapy available, and is based on McCullough's theory (McCullough, 2000). Establishing the extent to which McCullough's description of these individuals as interpersonally hostile and submissive is evidenced in the empirical literature will go some way to validating the theory and justifying the use of CBASP, which aims to help individuals move from a socially avoidant (hostile-submissive) interpersonal style to a more assertive and friendly one. The literature on attachment styles in depression provides some evidence of the role interpersonal processes play in the aetiology and



maintenance of depression, but to date, there appears to be a relative lack of literature exploring these correlates or underlying mechanisms in more detail. There is some evidence from the attachment literature that chronic forms of depression may be associated with different attachment styles from MDD, but again this has not been properly assessed. McCullough's theory, to date, has therefore not been properly tested. One recent study has set out to investigate the interpersonal styles of chronically depressed individuals, and provided some support for McCullough's hypothesis (Constantino et al., 2008). However the study used a convenience sample taken from a previous trial and used a small, non-randomised sample of healthy volunteers as a comparison condition. Another key gap in the literature is the apparent lack of research into factors, if any, that differentiate MDD from chronic depression.

This review aimed to assess whether the current literature supports the hypothesis put forth by McCullough, that individuals suffering from chronic depression exhibit a hostile-submissive, or socially avoidant, interpersonal style. Given the current evidence from the attachment literature of the association between depression and anxious and avoidant attachment, the review sought first to establish whether there is evidence that individuals with Major Depressive Disorder (MDD) would exhibit hostility and submissiveness. Secondly, in order to assess McCullough's hypothesis, the review sought to determine whether the extant literature supports the hypothesis that individuals with chronic depression are more hostile and submissive than those with MDD.

The review sought to test the following hypotheses:

1. MDD overall will be associated with both hostile and submissive interpersonal styles.

2. Chronic depression will show a greater association with hostility and submissiveness than MDD.

### **3.3. Methods**

#### **3.3.1. Search strategy**

The following databases were searched from inception, with searches covering up to January 2016: Embase (1980 – January 2016), Medline (1946 to January 2016), PsycInfo (1806 to January 2016), ASSiA (1984 to January 2016), CINAHL (1937 – January 2016). Searches sought to identify studies that reported a relationship between depression in individuals with MDD with measures of hostility and submissiveness. Searches sought to identify studies relating to ‘depression’ (depression, depressed, depress\*), and search terms were combined using AND to terms relating to ‘submissiveness’ (submissiveness, submissive, submiss\*, agency, assertive\*, dominant, dominance, power, passiv\*) OR ‘hostility’ (hostility, hostile, hostil\*, friendliness, unfriendly, communion, cold\*) OR ‘Interpersonal’ (interpersonal, interpersonal circumplex, impact message, interpersonal style). Other appropriate search terms as identified by the individual databases were also included.

#### **3.3.2. Inclusion criteria**

The inclusion criteria of the review stipulated that studies had to be published in English, and using a sample of adults (aged 16 and above) with a primary diagnosis of Major Depression, established prior to the research commencing. Included studies also required a validated measure of either submissiveness, hostility, or both. Studies using a single item from a validated scale would be excluded. Both self-report and

clinician/significant other rated measures were included. Only peer-reviewed research published in academic journals was included.

For the review, MDD was defined as having been assessed and found to meet diagnostic criteria for Major Depression based on either DSM or ICD-10 criteria. Chronic Depression was defined as a depressive episode lasting two years or longer, where the individual has experienced previous episodes. This included Chronic MDD (lasting 2 years or longer), recurrent MDD with a continuous duration two years or more, dysthymia, or MDD with pre-existing dysthymia (Double Depression). In line with the Interpersonal Circumplex, Interpersonal submissiveness was defined as low assertiveness and agency, while interpersonal hostility was defined as avoidance of others and a lack of warmth towards others. Hostile-submissiveness was defined as social avoidance.

### *3.3.3. Exclusion criteria*

Studies were excluded if the diagnostic status of the sample was established post-hoc simply by using cut-off scores on measures of depression, or where papers used non-clinical samples. Papers were also excluded if they did not use quantitative data or reported single cases. Non peer-reviewed research including dissertations and book chapters was excluded, as were papers not published in the English language.

### *3.3.4. Summary of searches*

Figure 1 presents a flowchart of the search process. The initial literature searches yielded a total of 4112 results (783 from Embase, 688 from Medline, 1629 from PsycInfo, 651 from ASSiA, and 361 from CINAHL). A total sample of 3003

studies was retained after deduplication. Firstly, titles of included studies were screened, after which 253 studies were retained. Abstracts of these studies were then screened, leaving a final sample of 40 studies (29 Major Depression, 11 Chronic Depression). Full texts of these were then reviewed. One study was excluded as it presented the results of the same sample as an earlier study (Constantino et al., 2008), 14 were excluded because they did not use validated measures of hostility or submissiveness, 5 were excluded because they did not report the associations between measures, 6 did not present adequate data to establish diagnostic status, 2 used samples of recovered MDD patients, and 4 studies were excluded because they did not report a comparison group. Twelve studies were included in the systematic review, and 8 of these were included in the meta-analysis. Of the studies included in the review, three included chronically depressed patients, and nine included patients with MDD as a primary diagnosis.

### *3.3.5. Quality assessment of included studies*

The studies included in the review were quality rated in relation to their suitability for addressing the aims of the current research. As the majority of quality rating instruments for systematic reviews focus on research evaluating effectiveness of interventions, these were not thought to be appropriate. A quality assessment measure was devised based on those used in previously published meta analyses and systematic reviews of observational study, and with reference to the recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) initiative (Matcham, Rayner, Steer, & Hotopf, 2013; von Elm et al., 2007). Seven items were devised, with the measure yielding a total quality score for each

study out of a maximum score of 12 (See Appendix A for the measure used). Table 1 presents a summary of the quality of each study, along with an overall quality score.

#### *Data extraction*

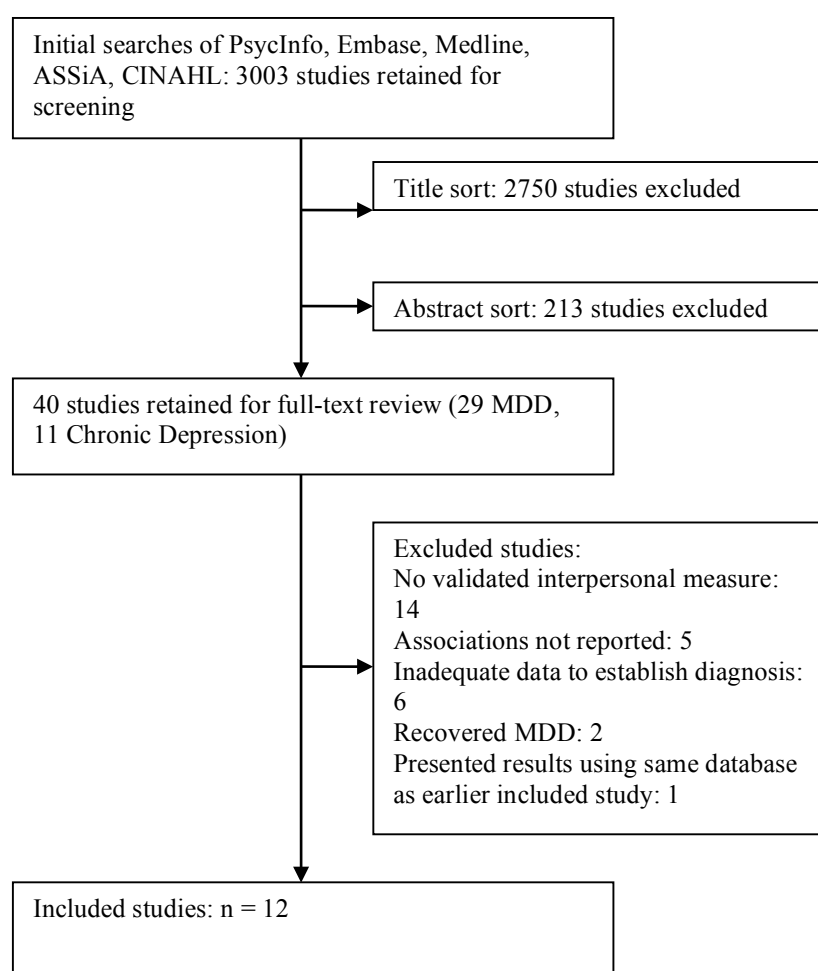
Extraction of information from studies was performed by the first author and checked by an independent rater (T.W.) using an extraction form. Discrepancies were resolved through discussion.

The majority of reviewed studies were cross-sectional and reported group comparisons between depressed individuals and controls. For these studies, therefore, Cohen's  $d$  was calculated. Where studies reported correlations,  $r$  values were converted to Cohen's  $d$  using a formula provided in Borenstein et al. (2009). Models were first run without including these studies, and studies were included if they did not significantly change the pooled estimates.

#### *3.3.6. Data analysis*

We employed meta-analysis to evaluate the size of the effect for interpersonal style on depression. Three analyses were carried out, for submissiveness, hostility, and for hostile-submissiveness. Moderator analysis were carried out to compare chronic depression with MDD where at least two studies provided suitable data for each subgroup. Where studies reported correlations rather than mean differences, correlation coefficients were converted to Cohen's  $d$  using the formula provided in Borenstein, Hedges, Higgins, and Rothstein (2009). Moderator analyses were conducted to evaluate their effect on the models, and where they did not alter the results substantially they were included in the reported analyses. Analyses were

undertaken using the Meta Analysis via Shiny package for R (MAVIS; Hamilton & Mizumoto, 2015). Random-effects models were used in order to take into account the heterogeneity of the sample of included studies (due to differences between samples, measurement instruments, etc).



**Figure 1.** Literature search strategy flowchart.

### **3.4. Results**

#### *3.4.1. Characteristics of included studies*

Characteristics of included studies are presented in Table 2. All studies presented cross-sectional data, with most utilising baseline data from randomised controlled trials, with data from normative studies as comparisons. All studies took place in Western countries (USA, Germany, UK). The main interpersonal measures were the Impact Message Inventory (IMI; therapist-completed) and the Inventory of Interpersonal Problems (IIP; self-report). One study used the Submissive Behaviour Scale (SBS; O'Connor et al., 2002), and two studies used the NEO Personality Inventory (NEO PI-R; Costa & McCrae, 1992). Three studies did not include any comparison groups (Cain et al., 2012; Dinger et al., 2015; Lam, Schuck, Smith, Farmer, & Checkley, 2003).

All studies were assessed in terms of quality for addressing the aims of the current review. None of the included studies scored above 8/12 for quality. No studies reported any power calculations, and only one study utilised a random sampling strategy. The majority of studies used either convenience samples or baseline data from intervention trials. Similarly, comparison conditions came from normative studies or convenience samples of healthy volunteers. Given that no studies reported power calculations, there is a possibility that samples were underpowered, especially to detect small or moderate effects. All studies employed validated measures of depression (BDI-II or HRSD) and interpersonal style (IIP, IMI, SBS, NEO PI-R). A sample of the included studies was rated for quality by an independent rater. Inter-rater reliability (Cohen's Kappa) was found to be 0.86, indicating outstanding agreement (Landis & Koch, 1977), with 90.5% agreement.

**Table 1.** Quality ratings of studies included in the review.

Study	Recruitment Strategy	Sample size calculation	Total N	Participation Rate > 75%	Depression measure	Interpersonal style measure	Eligibility criteria specified	Quality score
Bagby et al 1997	Not specified	Not reported	25 – 129	Yes	Clinical interview	Validated measure	Yes	6
Barrett and Barber 2007	Not specified	Not reported	500+	Yes	Clinical interview	Validated measure	Yes	8
Constantino et al 2008	Not specified	Not reported	130 – 499	Yes	Clinical interview	Validated measure	Yes	7
Gotlib and Whiffen 1989	Not specified	Not reported	25 – 129	No/Not reported	Clinical interview	Validated measure	Yes	4
Holtforth et al 2012	Not specified	Not reported	500+	Yes	Clinical interview	Validated measure	Yes	8
McCabe 1993	Randomised	Not reported	25 – 129	No/Not reported	Clinical interview	Validated measure	No	5
McCullough et al 1994	Not specified	Not reported	25 – 129	No/Not reported	Clinical interview	Validated measure	Yes	4
McCullough et al 1988	Not specified	Not reported	25 – 129	Yes	Clinical interview	Validated measure	Yes	6
O'Connor et al 2002	Not specified	Not reported	25 – 129	No/Not reported	Screening tool only	Validated measure	No	1
Lam et al 2003	Not specified	Not reported	25 – 129	Yes	Clinical interview	Validated measure	No	5
Dinger et al 2015	Not specified	Not reported	130 – 499	Yes	Clinical interview	Validated measure	Yes	7
Cain et al 2012	Not specified	Not reported	130 – 499	Yes	Clinical interview	Validated measure	Yes	7

### 3.4.2. *Interpersonal style in depression*

#### *Hostility*

The review found 11 studies that reported a relationship between hostility and depression. Three studies used chronic depression samples, with two finding large effects and one (McCullough et al., 1994) finding a small effect. All three of these studies reported comparisons between chronically depressed participants and non-clinical controls, though the comparison condition in one paper was made up of only 6 individuals who had previously experienced MDD and were in remission (McCullough et al., 1988). Eight studies were included which reported a relationship between hostility and MDD. Of these, four were cross-sectional studies comparing a



clinical sample against non-clinical controls, and four were cross-sectional studies without comparison conditions. Findings were mixed, with effect sizes of the association ranging from large (Gotlib & Whiffen, 1989) to small (Grosse Holtforth, Altenstein, Ansell, Schneider, & Caspar, 2012), and one study reported a weak negative association (Bagby et al., 1997). However the sample of this latter study was qualitatively different from the others in that it reported differences between high- and low-hostile patients with MDD, with those with lower scores reporting more depressive symptoms (compared to other studies that reported either correlations for a clinical sample or group differences between clinical and non-clinical participants). All studies used validated measures of hostility, including IIP, IMI, and NEO.

**Table 2.** Summary of included studies.

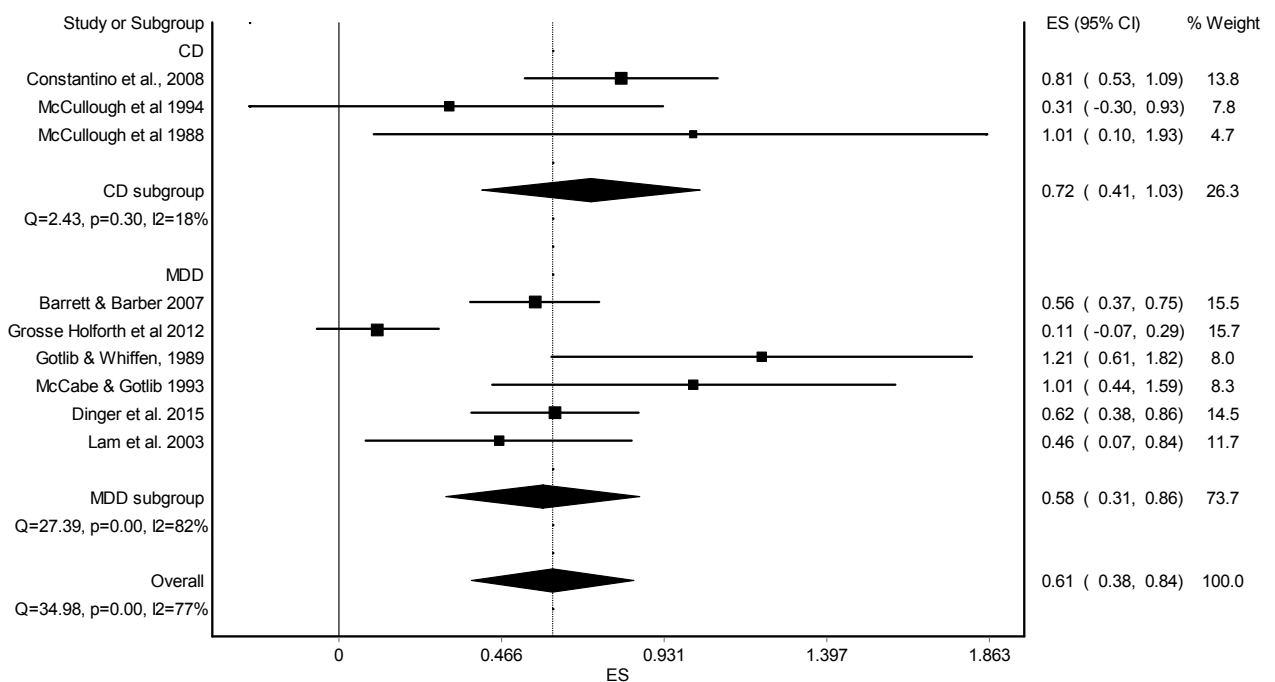
Author, country	Design	Sample (country, population, gender)	Age (mean, range)	Diagnosis	Depression measure	Submissivene ss measure	Hostile- submissiveness measure	Hostility measure
Constantino et al., 2008, USA	Cross-sectional	Chronic MDD, N = 442, 65.8% Female	43.9 (SD = 10.5, 18-75	Chronic MDD	HRSD	IMI	IMI	IMI
McCullough et al 1994, USA	Cross-sectional	n = 24. Dysthymia	39.7 (SD = 8.6), 19-73	Chronic depression,	HRSD	IMI	IMI	IMI
McCullough et al 1988, USA	Longitudinal	N = 34, dysthymia 76% female.	Mean age 31.7 years  M = 37.8 (SD = 12.1), 19-68,	Dysthymia, MDD	HRSD; BDI	IMI	IMI	IMI
Barrett & Barber 2007, USA	Cross-sectional	MDD, n = 141 (60% female); normative controls (n = 800)	controls n = 800 18 - 89, 50% female,	MDD	HRSD	IIP-C	IIP-C	IIP-C
Holforth et al 2012, Switzerland	Cross-sectional	MDD, N = 180 (58.9% female); comparison sample of outpatients with various diagnoses n = 491. 53.6% female	35.8 years (SD = 12.0), 15 - 80.	MDD	BDI	IMI	IMI	IMI

Author, country	Design	Sample (country, population, gender)	Age (mean, range)	Diagnosis	Depression measure	Submissivene ss measure	Hostile- submissiveness measure	Hostility measure
O'Connor et al. 2002, USA	Cross- sectional	n = 102; 50 inpatients with depression, 52 student controls; 52.9% female N = 52 (20 MDD inpatients and partners, 14 non-depressed inpatients and partners, 18 control couples), 47% female clinical samples	M nonpatient sample = 20.2 (SD = 2.6), patients = 39.2 (SD = 10.7) Age M = 46.15 (SD = 8.24), non- depressed (M = 40.89, SD = 6.89), range 18-60	MDD	BDI	SBS		
Gotlib & Whiffen, 1989, Canada	Cross- sectional			MDD	BDI	IMI	IMI	IMI
McCabe & Gotlib 1993, Canada	Cross- sectional	N = 53 females (n = 23 with MDD, n = 30 no depression)	Age (M = 29.0 for depressed sample, M = 28.5 non- depressed)	MDD	BDI	IMI		IMI
Bagby et al 1997, Canada	Cross- sectional	MDD patients. N = 125 (78 females), 51 included in analyses.	Age M = 34.3, SD = 9.2	MDD	HRSD			NEO
Lam et al 2003, UK	Cross- sectional	N = 109, 55% female	Age M = 44.4 (SD = 12.8)	MDD	BDI	IIP32	IIP32	IIP32

Author, country	Design	Sample (country, population, gender)	Age (mean, range)	Diagnosis	Depression measure	Submissivene ss measure	Hostile- submissiveness measure	Hostility measure
Dinger et al 2015, Germany/US A	Cross- sectional	MDD patients (n = 283), 63.6% female	Age (M = 36.9, 11.5)	MDD	BDI	IIP-C	IIP-C	IIP-C
Cain et al 2012, USA	Cross- sectional	N = 312 No information on gender	Age range 18-45	MDD	LIFE	NEO		

Measures: BDI: Beck Depression Inventory; LIFE: Longitudinal Interval Follow-up Evaluation; IIP: Inventory of Interpersonal Problems; IIP-C: Inventory of Interpersonal Problems – Circumplex Scale; IMI: Impact Message Inventory; HRSD: Hamilton Rating Scale for Depression; SBS: Submissive Behaviour Scale; NEO: Personality Inventory – Revised NEO

A meta-analysis was performed to determine the overall estimate of the relationship between hostility and depression. All studies were included where Cohen's  $d$  was calculable based on available data. Two were excluded (Bagby et al., 1997; Cain et al., 2012) as they did not provide adequate data to calculate an effect size. Two correlational studies were included in the analysis (Dinger et al., 2015; Lam et al., 2003), with the Pearson's  $r$  value converted to  $d$  using the formula provided in Borensetin et al. (2009). The Random Effects model revealed an overall effect size of  $d = 0.61$  (95% CI 0.38 – 0.84,  $N = 2516$ ,  $Q = 34.98$ ,  $p < .001$ ,  $I^2 = 77\%$ ). A moderator analysis revealed a larger effect for chronic depression (0.72, 95% CI 0.41 – 1.03,  $n = 407$ ,  $I^2 = 18\%$ ) than MDD (0.58, 95% CI 0.31 – 0.86,  $n = 2109$ ,  $I^2 = 82\%$ ), though both represented medium effect sizes.

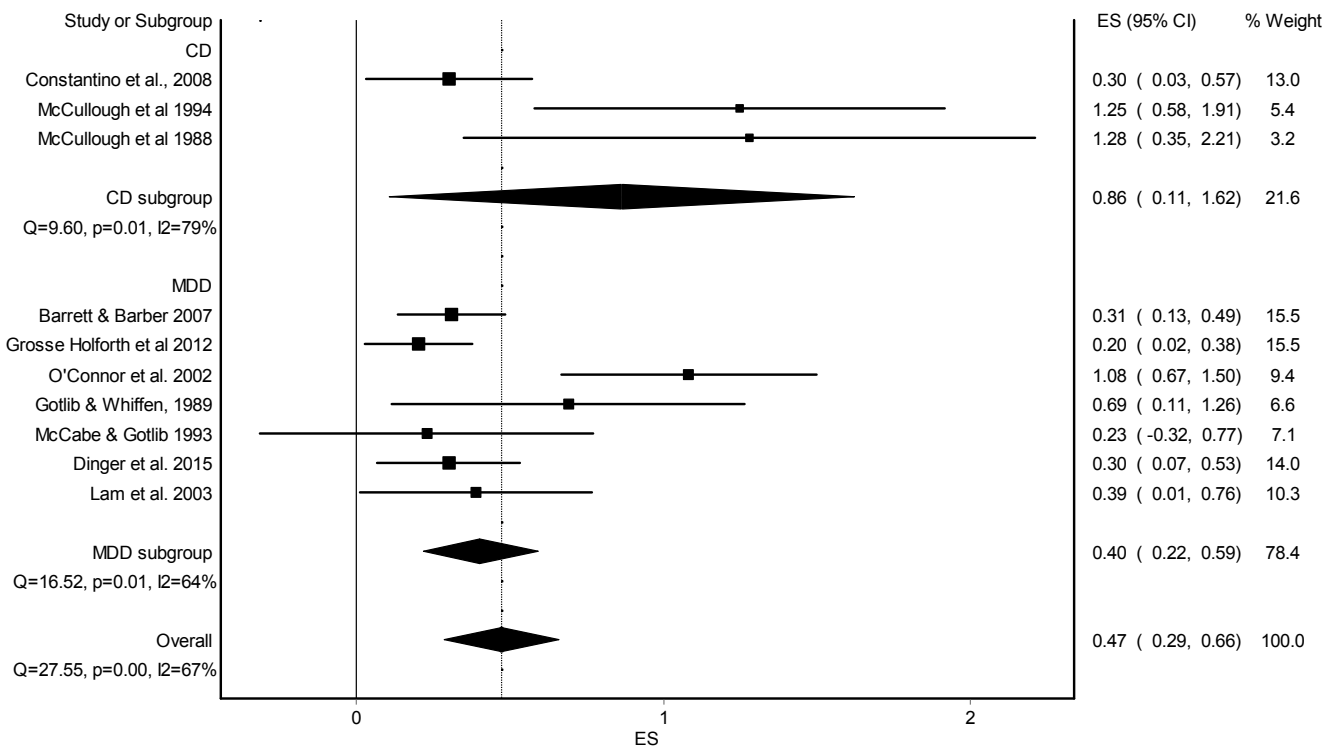


**Figure 2.** Random Effects meta-analysis for Hostility.

### *Submissiveness*

Eleven studies reported a relationship between depression and submissiveness. Again, three studies reported on samples of chronically depressed individuals while the rest included individuals with MDD. Studies used either the IIP, IMI, NEO, or SBS as measures of submissiveness. As with Hostility, studies reported a range of effect sizes varying from 0.2 to 1.31. One study reported that individuals with submissive personality type experienced more impaired functioning than other personality types (dominant, arrogant, cold, unassuming;  $d = 0.80$ ; Cain et al., 2012). This personality type was also found to be associated with chronicity of MDD ( $d = 0.86$ ) compared with all except hostile individuals. Overall, studies with larger sample sizes tended to report smaller effects of submissiveness on depression.

Of the studies included in the review, one was excluded from the meta-analysis (Cain et al., 2012) as it did not provide enough information to calculate Cohen's  $d$ . Two of the included studies reported correlation coefficients and regression coefficients which were converted to  $d$  (Dinger et al., 2015; Lam et al., 2003). The RE model found a pooled effect estimate of 0.47 (95% CI 0.29 – 0.66,  $N = 2615$ ,  $Q = 27.55$ ,  $p < .001$ ,  $I^2 = 67\%$ ). Moderator analysis again revealed a larger pooled estimate for chronic depression ( $d = 0.86$ , 95% CI 0.11 – 1.62,  $n = 404$ ,  $I^2 = 79\%$ ) than for major depression ( $d = 0.40$ , 95% CI 0.22 – 0.59,  $n = 2211$ ,  $I^2 = 64\%$ ).

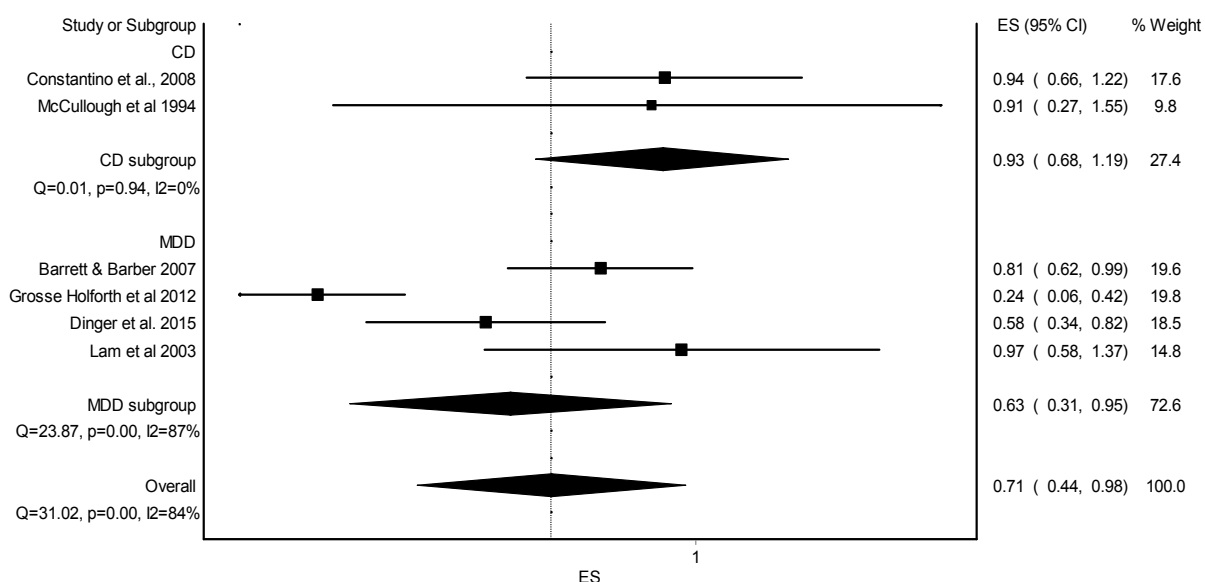


**Figure 3.** Random Effects meta-analysis for Submissiveness.

### *Hostile-Submissiveness*

A total of 6 studies in the review included a measure of hostile-submissive interpersonal style. Two of these used samples of individuals with chronic depression (Constantino et al., 2008; McCullough et al., 1994), and 4 included individuals with MDD (Barrett et al., 2007; Dinger et al., 2015; Grosse Holtforth et al., 2012; Lam et al., 2003). Both chronic depression studies reported large effect sizes for the association between depression and hostile-submissiveness, while there was some variation between MDD studies, with effects ranging from small to large. All studies included either the IIP or IMI as interpersonal measures. Two studies reported correlations (Dinger et al., 2015; Lam et al., 2003), and the rest reported mean difference between clinical samples and controls.

For meta-analysis, correlation values were converted to Cohen's  $d$  and included as they were not found to change the results. Meta-analysis yielded a moderate pooled effect size estimate ( $d = 0.71$ , 95% CI 0.44 – 0.98,  $N = 2376$ ,  $Q = 31.02$ ,  $p < .001$ ,  $I^2 = 84\%$ ). A subgroup analysis was again performed, and revealed a difference between the two diagnostic groups. For chronic depression studies, the effect size was large ( $d = 0.93$ , 95% CI 0.68 – 1.19,  $n = 372$ ,  $I^2 = 0\%$ ) whereas for the MDD studies there was a medium effect ( $d = 0.63$ , 95% CI 0.31 – 0.95,  $n = 2004$ ,  $I^2 = 87\%$ ).



**Figure 4.** Random Effects meta-analysis for hostile-submissiveness.

### 3.5. Discussion

The review aimed to establish to what extent submissiveness and hostility are present in Major Depression, and whether there is evidence of stronger effects for individuals with chronic depression compared with MDD. Systematic literature searches identified 12 studies meeting inclusion criteria for the systematic review. Meta-analyses were then carried out to establish the strength of the effect of hostility,



submissiveness, and hostile-submissiveness in this population. Each analysis included a subset of the studies in the review. The results of the meta-analyses provide some evidence that submissiveness and interpersonal hostility are elevated in individuals with MDD compared with non-clinical controls. Across all three analyses, subgroup comparisons showed a larger effect for individuals with chronic depression than for individuals with MDD, consistent with McCullough's (2000) theory of chronic depression. This difference was especially evident for studies that included a measure of hostile-submissive (socially avoidant) style, and for submissiveness, large effects were found for chronic depression, compared with medium effects for MDD.

The review appears to support the findings of previous research of associations between insecure attachment styles and depression (Besser & Priel, 2003; Brennan et al., 1998; Oliver & Whiffen, 2003; Roberts et al., 1996; Wei et al., 2004). Thus, the prevalence of hostile and submissive interpersonal styles in the MDD population may be associated with the attachment styles that are known to be a feature of depression. That individuals with chronic depression were found to exhibit higher levels of hostile-submissiveness provides some support for the hypothesis that chronically depressed patients have arrested maturational development characterised by preoperational thinking (McCullough, 2000, 2006; Swan & Hull, 2007). According to McCullough's theory, this would provide an explanation for the stronger effect in this population, as interpersonal hostile-submissiveness is seen as the product of long-term unresolved interpersonal difficulties. There was also some evidence that this interpersonal style was more prevalent in non-remitted MDD patients than those who remitted (McCullough et al., 1988), and that depressed individuals classified as submissive and hostile experienced greater chronicity of current episode than individuals classified as

extraverted, dominant, arrogant, or unassuming (Cain et al., 2012). There was evidence from one study that hostility might be what differentiates chronically depressed from acutely depressed patients. Constantino et al. (2008) found that these two groups did not differ in submissiveness, friendly-submissiveness, or hostile-submissiveness, suggesting that submissive behaviour might be related to depressive pathology more generally, in line with previous literature (Joiner, 2002; Segrin, 2001). The findings of this review, however, would suggest the opposite, with larger differences observed between chronically depressed individuals and acutely depressed individuals for submissiveness and hostile-submissiveness than for hostility.

The review yielded a relatively small number of studies, particularly relating to chronic depression. This may reflect that it is only relatively recently that authors have begun to identify how common recurrent MDD and chronic depression are (Lavori et al., 1994; Pincus & Pettit, 2001; Wells et al., 1992), and that this population has to date been generally under-researched and poorly understood (Constantino et al., 2008; Swan & Hull, 2007). Given the prevalence of chronic depression and the known consequences, including increased risk of unemployment, marital breakdown, lower socio-economic status, and increased use of health services, the review highlights a need for further research to better understand its aetiology (Swan & Hull, 2007; Wells et al., 1992).

### *3.5.1. Implications for treatment*

The review's findings could have important treatment implications. The analyses provide preliminary support for McCullough's theory of chronic depression. The findings that individuals with chronic depression exhibit predominantly

submissive and hostile interpersonal behaviours might be a manifestation of the kind of preoperational thinking that McCullough described in this population, but the current limited evidence base does not specifically support this. Given that one of the goals in CBASP is to identify the patient's impact message and then to help them move from preoperational thinking in the interpersonal domain into formal operational thinking, the strength of the effects found in this review provide some validation for this approach to treatment. This is also consistent with the IPT literature, where individuals within the interpersonal deficits focus area have been described as dependent and helpless which invokes feelings of hostility in others and leads to increased isolation, thereby contributing to the maintenance of depression (Lipsitz, 2009).

The general finding that individuals with clinical depression tend to behave in hostile and submissive ways has important implications for treatment generally. A patient behaving in a hostile manner will likely evoke feelings of hostility in his or her therapist, and similarly a submissive patient will likely evoke a feeling of dominance in the therapist (Horowitz, 2004; Kiesler, 1983). McCullough (2000) recommends that therapists complete the IMI early in treatment in order to form their own understanding of patients' interpersonal functioning. Doing so allows the therapist to identify the interpersonal 'pulls' of the patient and avoid reacting with complimentary hostility and dominance, in order to avoid perpetuating the patient's preoperational thinking. By understanding a patient's interpersonal style, the therapist can identify when feelings of hostility are being evoked, and instead adopt the more beneficial friendly interpersonal style (McCullough, 2000).

Interpersonal Psychotherapy (IPT) has a good evidence base for treating MDD (Cuijpers et al., 2011; van Hees, Rotter, Ellermann, & Evers, 2013). However studies into its effectiveness for chronic depression have yielded mixed findings (Cuijpers et al., 2010). However our findings are in line with the ‘Interpersonal Sensitivities’ focus area in IPT, which describes a difficulty in forming and maintaining relationships leading to social isolation and loneliness. Patients in this focus area have been described as exhibiting passivity and hostility in the therapeutic relationship (Wurm, Robertson, & Rushton, 2008). This IPT focus area shares with CBASP the goal of helping patients to start to discriminate between past maladaptive relationships and current relationships, and to start to gain an understanding of the interpersonal patterns that tend to impede the formation of relationships, including with the therapist. The review’s findings indicate that individuals with chronic depression would be likely to present with difficulties in this domain.

### *3.5.2. Limitations of the review*

The review’s findings are limited by a number of factors. Firstly, high levels of heterogeneity were found in all three meta-analyses. Subgroup analyses provided some explanation, with chronic depression generally showing less heterogeneity than MDD, though there were fewer studies. The small numbers of studies in the analyses precluded the use of meta-regression as a means of exploring the heterogeneity (Thompson & Higgins, 2002). However, the total samples for all of the analyses were large given the number of included studies. The high levels of heterogeneity reflect the limited research in this area, and the limited quality of the included studies. The majority of the studies in the review presented secondary analyses of data from RCTs

and case series, with either convenience samples or normative data from other studies as non-clinical control samples. This methodological diversity is likely to have contributed to the heterogeneity in the analyses. Overall, the high levels of heterogeneity highlight the need for well-designed, adequately powered studies in this area.

A second limitation of the review was the lack of studies comparing chronic depression and MDD. Only one study provided a comparison (Constantino et al., 2008). This absence of a direct comparison limits the conclusions we can draw in relation to the hypothesis that chronic depression would be associated with increased hostility and submissiveness compared with MDD. In addition, the quality of included studies varied, and most of the included studies had small, non-randomised samples.

### *3.5.3. Conclusions and recommendations*

The results of this review provide evidence that individuals with both major depression and chronic depression display a hostile submissive interpersonal style, supporting our first hypothesis. There was limited support for our second hypothesis that individuals with chronic depression would be more hostile-submissive than those with acute depression. Results in this area were limited by the lack of direct comparisons between the two clinical populations. The review and meta analysis revealed that the empirical research in this area is limited, with many of the studies included in the review using baseline data from intervention studies with normative samples as comparison conditions. Findings should therefore be interpreted in the context of these limitations. Further research is now needed in order to directly compare interpersonal styles of chronically depressed individuals with those with

MDD. There is a need for studies using robust recruitment methods, with clear reporting of power calculations. Additionally, given that CBASP is designed specifically to engage individuals with hostile-submissive interpersonal styles, research into its ability to engage and retain these patients would provide a potential validation of the therapeutic model.

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#### **4. Chapter 2: Journal Article**

##### **What is the process of change in Cognitive Behavioural Analysis System of Psychotherapy? Findings from multilevel modelling analyses in two samples**

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#### **4.1. Abstract**

There is a growing body of evidence that Cognitive Behavioural Analysis System of Psychotherapy (CBASP) is an effective intervention for treating chronic depression. However, few studies to date have sought to establish the evidence for the theoretical model on which CBASP is based. This paper presents two studies investigating aspects of the model. In Study 1, multilevel modelling analyses were applied to data from a case series ( $n = 52$ ) to investigate whether symptom change during therapy was associated with acquisition learning in relation to the therapy goals, and whether interpersonal style affected individuals' likelihood to respond to treatment. Study 2 presents preliminary data from a multiple-baseline, small-N study ( $n = 13$ ) which aimed to model within-participant symptom change during CBASP, and to investigate whether the interpersonal component of CBASP (Disciplined Personal Involvement; DPI) affects change. Findings from Study 1 supported the hypothesis that acquisition learning would be associated with symptom change in CBASP, particularly relating to the Situational Analysis exercise. Interpersonal style was not found to affect treatment response. Findings in relation to the process of change were mixed. Both studies provide evidence that individuals experience symptom change as a result of acquisition learning in CBASP. Incomplete data in Study 2 limits conclusions in relation to the role of DPI in CBASP. However preliminary evidence suggests that CBASP without DPI was associated with limited symptom improvement early in therapy, compared with regular CBASP. The use of multilevel modelling to analyse single-case data provided some advantages over visual analysis in Study 2.

**Keywords:** Chronic Depression; CBASP; Therapeutic change; Multilevel Modelling; Single-case designs.

## **4.2. Introduction**

Along with anxiety, depression is widely recognised as one of the most common mental health problems, with 1 in 5 individuals in the UK reportedly experiencing at least one episode in their lifetime (ONS, 2013). Depression represents a particular challenge to health services because of its resistance to treatment, and its chronicity. Findings suggest that 40% of individuals diagnosed as experiencing depression will continue to meet criteria one year on, and up to 20% of those who meet criteria for major depression will experience episodes lasting over two years (Keller et al., 1992). In addition, nearly two-thirds of those who experience an episode of depression will experience a subsequent episode, and the chances of recurrence increase with each new episode (Lavori et al., 1994; Pincus & Pettit, 2001; Williams et al., 1997). Chronic depression is associated with time spent off work, unemployment, marital breakdown, and deterioration in socio-economic status (Wells et al., 1992). It is also associated with frequent use of medical services, and it is therefore essential to be able to provide effective treatments for these individuals which aim to treat not only the current episode but that can also reduce the risk of future episodes (Swan & Hull, 2007; Wells et al., 1992).

In the UK, treatment guidelines for individuals experiencing severe depression suggest the use of a combination of anti-depressant medication along with either cognitive behaviour therapy (CBT) or interpersonal therapy (IPT)(National Institute for Health and Clinical Excellence, 2009; The Matrix, 2015). This is in line with evidence, which suggests that for chronic major depression combination treatment is associated with the best outcomes (Arnow & Constantino, 2003). Miller, Norman and Keitner (1999) found that individuals treated with a combination of CBT and

pharmacotherapy experienced significantly greater improvement in depression symptoms at post-treatment follow-up than those treated with medication alone. However they found overall low response rates (38%) and high relapse over 1 year follow-up, so that there was no difference between conditions after 12 months. In addition to CBT and IPT, there is also evidence that the Cognitive Behavioural Analysis System of Psychotherapy (CBASP) is effective when combined with medication (Arnow & Constantino, 2003; Keller et al., 2000). In a multi-centre randomised controlled trial, combination treatment (CBASP with nefazodone) was associated with a higher treatment response (75%) than either therapy alone (~50%) at the end of treatment (Keller et al., 2000). However this study was limited by a lack of long-term follow-ups. Some authors have questioned whether IPT, which was originally developed to treat acute major depressive episodes, is actually as effective for individuals experiencing chronic depression (Schramm et al., 2011). In fact there is some evidence that the effectiveness of both IPT and CBT are limited for this population (Agosti & Ocepek-Welikson, 1997; Markowitz et al., 2005). In contrast with CBT and IPT, CBASP was developed specifically for use with individuals experiencing chronic depression.

#### *4.2.1. Cognitive Behavioural Analysis System of Psychotherapy (CBASP)*

CBASP is a manualised psychotherapeutic treatment for chronic depression (McCullough, 2000, 2006). It utilises a combination of cognitive, behavioural, and interpersonal techniques which are also used in therapies such as CBT and IPT. Central to CBASP is the idea that those who experience early onset chronic depression have experienced “maltreatment or lower-grade but protracted decrease or absence of



nurturing...thought to have led to an arrest of the cognitive-emotive maturational process at the Piagetian preoperational stage of development” (Swan & Hull, 2007, p. 459). There is an emphasis on teaching clients their ‘stimulus value’ within their environment by helping them to evaluate the consequences of their interpersonal behaviour. A transference hypothesis is constructed with the client early on in therapy which is used to identify ‘hot spots’ in the client’s interpersonal behaviour which are actively addressed when they occur. In this way the therapist practices disciplined personal involvement in relation to the transference hypothesis, the aim of which is to help clients to see the consequences of their interpersonal behaviour, and “allows them the opportunity for a new interpersonal reality” (Swan & Hull, 2007, p. 460). Disciplined personal involvement is considered a unique feature of CBASP. The aim in CBASP therefore is for the therapist to help the client to see how cognitive and behavioural factors can cause and maintain interpersonal problems, and to learn how to alter these using techniques such as interpersonal problem-solving and modelling.

#### *4.2.2. Evidence base for CBASP*

CBASP has been evaluated using a number of methodologies, including case series, open trials, and randomised controlled trials. The bulk of the evidence base comes from a large multi-centre randomised controlled trial which compared CBASP with antidepressant medication for treating individuals with early onset chronic depression (Keller et al., 2000). In this trial, participants were randomised to receive either CBASP, nefazodone, or a combination of the two. The study found that CBASP and nefazodone led to equivalent improvement, but that the combination treatment

provided the highest rates of improvement (73% in this group, compared with 48% in both treatment groups).

A crossover randomised controlled trial compared CBASP with nefazodone for chronically depressed individuals who had not previously responded to the other treatment (Schatzberg et al., 2005). Their results indicated that in both conditions, the change from one intervention to the other was associated with significant symptom improvements. Based on these findings, it appears that CBASP can be an effective treatment option for individuals resistant to antidepressants, and vice-versa. Although the study was limited by the lack of a placebo control, the use of a single antidepressant, and by a disproportionate drop-out rate in the group who received CBASP first, the results do support evidence from the earlier trial that CBASP can be effective for treatment resistant chronic depression.

CBASP has been compared with IPT in a randomised controlled trial (Schramm et al., 2011). Though the study included only a small sample ( $n = 30$ ), CBASP was found to be equivalent to IPT in bringing about improvements in symptoms of depression. This study provides preliminary evidence that both of these approaches can be beneficial for chronic depression. A recent case series in a sample of 74 participants found that for the 46 who completed the study CBASP was associated with a 30% remission rate, with another 30% of participants experiencing clinically significant change (Swan et al., 2014). Although this study had several limitations, including a lack of randomisation and no blinding, it provided some evidence that CBASP is an acceptable treatment for individuals with chronic depression and may be beneficial when delivered in routine care when offered over a period of 6 months with a maximum of 20 hours of therapy. Another recent trial in

which participants were offered fewer than 13 sessions of CBASP found that CBASP was not associated with any significant effects over medication alone (Kocsis et al., 2009). It appears, therefore, that CBASP provides the most benefit when delivered over approximately 20 sessions and in combination with medication, although the current evidence base is limited by a lack of long-term follow-ups, and there is a consistent finding that around one-third of participants do not improve (Keller et al., 2000; Schatzberg et al., 2005; Swan et al., 2014).

#### *4.2.3. Limitations of evidence and new directions*

Despite the growing evidence base for CBASP, the research to date has been limited to randomised controlled trials or case series. These designs provide evidence that CBASP is associated with effects across treatment groups. However they do not provide any indication of individuals' variations in their response to treatment, and crucially, they do not provide an explanation of the process of change (Barlow & Hersen, 1973; Medical Research Council, 2008). Understanding the process of change in psychotherapy is essential for ensuring interventions are delivered optimally, and can also provide a further understanding of the aetiology of the disorder. McCullough *et al.* (2010) provide a methodology for carrying out Stage I research with single participants to understand the mechanisms of change in CBASP. Specifically, whether one or both of the learning goals (learning to experience safety with the clinician; learning to recognize interpersonal consequences of behavior; McCullough et al., 2010) are the mechanisms of change. For example, McCullough (2000) describes chronically depressed individuals as displaying preoperational thinking in the interpersonal domain, and hypothesizes that achieving the learning goals in CBASP

will facilitate a shift to formal operational thinking, where the patient begins to discriminate between current relationships and maltreating significant others. This shift would then lead to more positive and fulfilling interpersonal interactions, which in turn would lead to symptom improvements. Understanding how these key features of CBASP are related to psychological change in therapy can provide important information about how CBASP works, and could also help identify individual characteristics of participants that might facilitate or hinder change.

#### *4.2.4. The current study*

Single-case research is relatively common in drug trials where participants are alternated between the target intervention and a control, effectively acting as their own controls. However they are less common in research on psychological interventions. Despite this they do offer a number of potential advantages. As mentioned above, research using a single participant can provide information on the process of change during psychotherapy, as well as providing the ability to measure the effects of within-participant factors on outcomes. This paper presents two studies that both attempted to investigate the process of change in CBASP. Study 1 presents a multilevel modelling analysis of change during therapy for a sample of chronically depressed individuals taking part in a case series of CBASP. The aim of this study was to investigate the process of change, and the impact of acquisition learning in bringing about symptom reductions during therapy. Study 2 then uses a single-case design to investigate the process of psychological change for individuals with chronic depression who receive CBASP. By collecting symptom ratings at every session, this study aimed to provide a more detailed analysis of within-participant change than was

possible in Study 1. This study also utilised a multiple-baseline design in order to control for regression to the mean and natural recovery, and randomised participants to receive either CBASP or CBASP without the interpersonal component. By providing measurements of symptoms at each session, the effects of the different components of the therapy can be measured.

### **4.3. Study 1**

Study 1 aimed to investigate the process of change during CBASP for a sample of chronically depressed individuals. Based on McCullough et al.'s (2010) hypothesis, we would expect individuals to experience greater gains in the latter parts of therapy once learning had taken place in relation to Situational Analysis and Interpersonal Discrimination Exercise. We sought to investigate this hypothesis by fitting multilevel models for all participants to determine whether change in symptom scores was linear or non-linear, as would be expected. We also sought to investigate the effect of acquisition learning on symptom changes by adding measures of learning to the models and testing their effects. We hypothesised that learning in relation to Situational Analysis would be associated with symptom improvements as this is the primary active component of the therapy. We also expected that learning in the interpersonal domain (the Interpersonal Discrimination Exercise) would be associated with change. Finally, we investigated whether a hostile-submissive interpersonal style, as described by McCullough (2000), was associated with symptom levels, and whether it affected individuals' likelihood of experiencing symptom improvements in therapy.

#### *4.3.1. Methods*

##### *Participants*

The sample analysed in this study comes from a case series evaluating outcomes of individuals with chronic depression receiving CBSAP (Swan et al., 2014). Participants were recruited from secondary care mental health services in the UK and met criteria for chronic depression. A total of 115 referrals were screened for eligibility, of which 74 attended a pre-therapy baseline assessment, and 55 engaged in therapy ( $n = 46$  provided complete outcome data). Age ranged from 18 to 72 years ( $M = 44.00$ ,  $SD = 10.27$ ), and 68% of the sample were female.

##### *Procedure*

The procedure is described in detail in Swan et al. (2014). All participants were asked to attend a baseline assessment prior to beginning treatment. Participants were then offered CBASP, which was delivered according to a standard protocol consisting of up to 20 sessions over a 6-month period. A total of 11 therapists took part in the study, all of whom were trained in CBASP. Therapists consisted of 2 clinical psychologists, 8 were mental health nurses, and 1 was a psychiatrist.

Participants completed a number of measures at baseline, which were then repeated throughout treatment. The Beck Depression Inventory (BDI-II; Beck, Steer, Ball, & Ranieri, 1996) provided a measure of depression. It was administered at baseline, start of treatment, and at every fifth session, and then again post-therapy. The Inventory of Interpersonal Problems (IIP-64; Horowitz, Alden, Wiggins, & Pincus, 2000) provided a measure of interpersonal style and was administered at baseline. The PQ-SA and PQ-IDE (McCullough, 2006) provided measures of

acquisition learning in relation to the two goals of CBASP, and were administered throughout therapy. The PQ-SA was administered at sessions 2, 6, 10, 14, and 18, and the PQ-IDE was administered at sessions 4, 8, 12, 16, and 20.

### *Analysis Plan*

Analyses in this study were carried out using IBM SPSS (version 22). All available data was included in analyses. Linear mixed models were constructed to test the study hypotheses. Model fit was assessed using the -2 Log-Likelihood statistic (-2LL), which measures deviance. A smaller deviance indicates an improvement in model fit, and where possible chi-square tests were carried out to test for significance of model differences.

### *4.3.2. Results*

#### *Sample characteristics*

Of the original baseline sample, 52 were included in the present analyses. All individuals had completed between 4 and 20 sessions of therapy. For the study, the mean number of sessions attended was 16.40 (SD = 4.60).

Swan *et al.* (2014) reported the outcomes from the case series, with a large effect observed between pre-treatment and post-treatment ( $d = 1.03$ ). Of those who completed between 4 and 20 sessions, at the end of treatment 30.4% were found to be in remission from depressive symptoms as measured on the Hamilton Rating Scale for Depression (score of 8 or below), 30.4% had experienced clinically-significant improvement (a score of 15 or lower with a 50% reduction in score), and 39.2% were found to have experienced no change.

Hypotheses:

1. Change in depression over the course of therapy will follow a non-linear course, with more change occurring later in therapy
2. As functioning on Situational Analysis and Interpersonal Discrimination Exercise tasks improves, symptoms will decrease
3. We also sought to explore whether a hostile-submissive interpersonal style at baseline would have an effect on change during therapy

First, a model was constructed to test the effect of time on symptoms (BDI-II). A second model was constructed with a quadratic time function in order to test for non-linearity. Comparison of the model fit statistics revealed a significantly better fit for the linear model ( $-2LL$  change ( $df = 1$ ) = 102.80,  $p < .001$ ), suggesting that symptom change in CBASP was linear. The remainder of the analyses therefore tested linear models. The time effect was significant and negative ( $B = -2.33$ ,  $t(43.91) = -6.69$ ,  $p < .001$ ), reflecting a decrease in symptoms of depression over the course of the intervention. In addition, the slope variation term was found to be significant ( $B = 4.60$ ,  $p = .001$ ), suggesting that there was significant variation in symptom improvement between participants. The covariance between slope and intercept, however was not significant ( $B = -1.65$ ,  $p = .67$ ), suggesting that initial level of symptoms did not affect symptom improvement. Because of the repeated measures, a term was added to the model to explore autocorrelation within subjects' data. This revealed a significant  $\rho$  parameter ( $\rho = 0.20$ ,  $p = .03$ ), indicating a significant



positive relationship between participants' mood ratings at adjacent time points. Adding this term to the model produced a small improvement in model fit over the independence model (-2LL reduced to 2963.54). Table 1 provides a summary of this model.

We hypothesised that learning in relation to Situational Analysis and Interpersonal Discrimination Exercise tasks would be associated with symptom improvement. PQ-SA and PQ-IDE were added to the model to test this effect. Adding these two variables improved the model fit (-2LL = 2590.22 (df = 17),  $X^2 = 373.32, p < .001$ ). PQ-SA was found to have a significant effect on symptom severity, with those achieving recovery-level functioning experiencing lower symptom levels ( $B = -18.28, t(175.97) = -4.08, p < .001$ ). However, IDE learning was not found to substantially affect symptoms. Additionally, learning was not found to account for the variation in the slope of the time variable, which remained significant ( $B = 4.29, p = .001$ ). Adding baseline social avoidance (hostile-submissive style) as a predictor further improved model fit (-2LL = 2569.87). Hostile-submissiveness was found to be a significant predictor of symptom levels ( $B = 0.46, t(48.74) = 4.62, p < .001$ ). There was no interaction between this variable and time ( $B = 0.03, t(48.18) = 0.96, p = 0.34$ ), suggesting that this association remained stable throughout the course of treatment.

#### *4.3.3. Conclusions*

This study sought to determine whether individuals taking part in a case series of CBASP experienced symptom improvement gradually or whether, as predicted by the model, there would be greater gains later in therapy. We further sought to determine whether learning in relation to SA and IDE, and a hostile-submissive interpersonal style impacted on symptom change. The results revealed that overall, change was

linear, suggesting that most participants experienced gradual improvement in symptoms. However there was significant variation in the rate of change between individuals, suggesting that between-participant differences may affect their experience of symptom improvement in CBASP. This model did reveal that there was no relationship between initial symptom level and rate of improvement in CBASP. This provides an indication, in the absence of a control condition, that improvement was not due to regression to the mean, where those with higher initial symptom scores would be expected to experience greater improvement (Barnett, van der Pols, & Dobson, 2005).

**Table 1.** Summary parameters for the analyses.

	Beta	SE	DF	<i>t</i>	<i>p</i>
<i>Hypothesis 1</i>					
Intercept	38.44	1.27	73.18	30.25	< .001
Time	-2.33	0.35	43.91	-6.69	< .001
<i>Hypotheses 2 &amp; 3</i>					
Intercept	2.97	8.25	52.13	0.36	0.72
Time	-2.75	2.52	53.26	-1.09	0.28
PQ-SA	-17.56	4.3	167.36	-4.08	< .001
PQ-IDE	5.2	2.91	95.37	1.79	0.08
Socially Avoidant	0.46	0.1	48.74	4.62	< .001
Time*PQSA	1.8	1.05	200.91	1.71	0.09
Time*PQIDE	-1.96	1.09	229.64	-1.79	0.07
Time*Soc. Av.	0.03	0.03	48.18	0.96	0.34

The second model tested the hypothesis that learning in relation to the two goals of CBASP would precede symptom change during therapy. Adding these variables produced a substantial improvement in model fit over the null model, but only SA learning was found to be a significant predictor of symptom improvement. Adding baseline hostile-submissiveness further improved the model. As predicted,

hostile-submissiveness was associated with higher levels of depression, but individuals high in hostile-submissiveness did not appear to experience change differently from others.

The results in relation to the hypotheses are therefore mixed. The analyses did not find evidence to support the prediction that individuals would experience larger gains later in therapy. However there were relatively few time-points, which may mask more nuanced changes. The second hypothesis was partially supported, with both PQ-SA and PQ-IDE providing an improvement in model fit. However only PQ-SA was found to be a significant predictor of symptom reduction, and the interaction with time failed to reach significance. Results did not support the third hypothesis, that high hostile-submissiveness at baseline would be associated with less symptom change over therapy. This was associated with overall symptom levels, but the interaction with time was non-significant, suggesting that high hostile-submissiveness did not limit the effectiveness of CBASP.

Together these results provide some support for the CBASP model. CBASP appeared to provide a beneficial treatment for socially avoidant individuals who would be expected to find engaging in therapy challenging (Constantino et al., 2008; McCullough, 2000). In addition, measures of learning were found to account for substantial variance in the model. The finding that PQ-SA but not PQ-IDE learning was associated with symptom improvement is important to clarify, as there could be implications for the future development of CBASP. Further research is therefore needed to evaluate whether providing CBASP without using IDE leads to similar symptom change as when both SA and IDE are used. Further studies would also

benefit from more time-points in order to clarify the finding that change was linear and constant.

#### **4.4. Study 2**

Study 2 sought to address some of the findings of the first study. In particular, we sought to investigate further whether individuals would experience change similarly when receiving CBASP without IDE, compared with CBASP as usual. This study also aimed to address some limitations of the first study by collecting symptom data at every therapy session, and by including a baseline period. This study used a single-case design, with the aim of modelling symptom change within participants in more detail than was possible for the sample in Study 1. We further aimed to evaluate the use of recently-suggested statistical methods for analysing single-case designs by applying multilevel modelling techniques to the data, rather than relying on the traditional method of visual analysis (Shadish, Kyse, & Rindskopf, 2013; Shadish & Sullivan, 2011; Sullivan, Shadish, & Steiner, P.M., 2015; Van den Noortgate & Onghena, 2003).

##### *4.4.1. Methods*

###### *Participants*

Participants were 13 individuals recruited from two secondary care psychological therapy departments in NHS Scotland. Individuals were invited to take part if they were on the waiting list of the participating services for help with long-standing depression. Newly referred patients were also invited to take part if they met inclusion criteria for the study. The sample was made up of 10 women and 3 men, and

ages ranged from 32 years to 61 years ( $M = 47.64$ ,  $SD = 10.19$ ). Seven therapists participated in the study. All had completed CBASP training and were accredited CBASP practitioners.

### *Design*

The study used a single-case experimental design to investigate the process of symptom change for individuals receiving CBASP. A multiple baseline approach was used to establish baseline levels of depression for each participant, which allowed the effect of the intervention to be investigated in relation to pre-therapy levels of depression. Participants received one of two interventions: CBASP; CBASP without disciplined interpersonal involvement by the therapist. The study employed a quasi-randomised design where therapists were randomly allocated to provide one of the two conditions, and participants were assigned to therapists based on availability.

### *Inclusion Criteria*

Potential participants were included in the study where they met the following criteria:

- Have been depressed for 2 years or longer
- Have had previous episodes of depression
- Previous treatment (medication, psychotherapy, or both) has been unsuccessful or the participant has experienced relapse

### *Exclusion Criteria*

Individuals were not considered for participation if they had received psychological therapy in the 12 months leading up to the study; had significant current

substance misuse; had a diagnosed learning disability; where psychosis was present. In addition, due to the constraints of the study it was not possible to include individuals who could not read, write, and speak English, or who were unable to commit to the full duration of the research.

### *Materials*

*PHQ-9* (Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a nine-item self-report measure of depression, where each item represents diagnostic criteria. Participants rate the frequency that each item has occurred over the preceding two-week period. Ratings range from “0” (not at all) to “3” (nearly every day). Scores are summed to yield a total score of depression severity ranging from 0 to 27. Cut-offs 5, 10, 15 and 20 represent mild, moderate, moderately severe, and severe depression, respectively. The scale has been found to have good psychometric properties.

*Personal Questionnaire – Situational Analysis (PQ-SA; McCullough, 2006)*. Three sentences are constructed with the client. They reflect a specific behaviour and denote illness-level functioning (e.g. “very rarely do I recognise the interpersonal effects I have on others”), improvement-level functioning (e.g. “sometimes I recognise the interpersonal effects I have on others”), and recovery-level functioning (“I usually recognise the interpersonal effects I have on others”; McCullough, 2006). The client performs a paired comparison task where one sentence is selected from each of the three comparisons based on how they see themselves behaving right now.

*Personal Questionnaire – Interpersonal Discrimination Exercise (PQ-IDE; McCullough, 2006)*. As with the PQ-SA, three sentences are constructed reflecting

illness-level, improvement-level, and recover-level functioning. In the PQ-IDE these relate to discrimination functioning in relation to the transference hypothesis (e.g. “I feel my therapist will end up being like, or behaving toward me like [significant others]”; McCullough, 2006). Again the client selects one statement in each paired comparison.

*Inventory of Interpersonal Problems (IIP-32; Barkham, Hardy, & Startup, 1996).* A 32-item measure of an individual’s difficulties in interpersonal relationships. Items are scored in relation to the amount of distress caused by each item on a 5-point Likert scale ranging from 0 (“not at all”) to 4 (“extremely”). The scale includes 8 subscales representing difficulties with assertiveness, being sociable, being supportive, and being involved; and spending too much time being dependent, caring, being aggressive, and being open. The measure has been found to have good internal reliability, with alpha coefficients for the subscales ranging from .71 to .89, and .90 for the full scale (Barkham et al., 1996).

### *Interventions*

#### Cognitive Behavioural Analysis System of Psychotherapy (CBASP)

CBASP is a form of therapy specifically designed to treat individuals with chronic depression. CBASP combines a number of elements, with a focus on teaching the client to become aware of their interpersonal behaviour and its consequences. This is achieved through Situational Analysis which is used to elicit psychopathology within sessions and to identify problematic behaviours which can be addressed in therapy. In addition to situational analysis, in CBASP the therapist practices disciplined personal involvement (DPI), which is a unique feature of the therapy

wherein the therapist uses the therapist-client relationship to address a ‘transference hypothesis’ constructed using the client’s significant other history. The function of this hypothesis is to highlight the learned responses of the client, and work in therapy focuses on helping the client to discriminate between previous maladaptive relationships and the current therapeutic relationship.

In this study two versions of CBASP were provided. The first was CBASP as described above. In the second condition CBASP was delivered without Disciplined Personal Involvement (DPI) by the therapist. The reason for including this condition was to investigate whether DPI affects the process of psychological change in CBASP.

Those receiving CBASP without DPI completed all of the same exercises within therapy, but instead of using the therapist-client relationship, the therapist and client used other relationships in the client's life to provide this focus.

### *Procedure*

The study received ethical approval from an NHS Research Ethics Committee (Appendix E), and management approval from NHS Lothian and NHS Tayside (Appendix F). The protocol was registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (University of Edinburgh Protocol Record 15/WS/0027).

Participants were recruited from two Scottish secondary care psychology services. Potential participants were either already on the service waiting lists for treatment of chronic depression, or were new referrals presenting with chronic depression. Service clinicians initially identified potential participants and sent them a letter of invitation along with a Participant Information Sheet (Appendix B & C). Individuals were then requested to contact the service if they wished to participate.



New referrals who attended an initial assessment appointment with a service clinician were informed of the study if the clinician considered that they met inclusion criteria. Individuals had the option of opting in to be contacted directly by the researcher, or they could take away the information and consider their decision prior to opting in.

All participants who opted into the study were offered an hour-long initial appointment with the Chief Investigator. The purpose of this appointment was to discuss participation and answer any outstanding questions prior to providing written consent to participate. A baseline assessment was then completed, consisting of the HRSD, IIP-32, a demographics questionnaire, and the PHQ-9. Dated copies of the PHQ-9 were then provided for participants to complete once a week for the following three weeks prior to beginning treatment.

All participants in both conditions were offered up to 20 sessions of therapy over a 6 month period. Therapy was delivered according to a protocol developed prior to the beginning of the study, and derived from that used in a previous case series (Swan et al., 2014). The PHQ-9 was administered at every therapy session for each participant. Participants were invited to attend a follow-up assessment 6 weeks after the end of therapy, where the HRSD, PHQ-9, and IIP-32 were administered.

#### *Sample size and data analyses*

Although there are currently no specific guidelines as to sample sizes for this type of analysis for Single-Case Designs, Shadish and Sullivan (2011) published a survey of single-case studies and found that the modal single case study included three cases with 20 data points. Shadish, Kyse, and Rindskopf (2013) reviewed the current

literature on power for this type of design and found no studies that have addressed this question properly. However there is evidence that using as few as six cases with 30 observations would allow for the detection of significant between-case variance components (Van den Noortgate & Onghena, 2003). The sample size for the current study was decided upon based on feasibility as the aim was to investigate individuals' experience of change within CBASP. However, analyses will also allow us to investigate the power of this type of design for assessing both within-participant change and between-participant variance, and may in fact contribute to our understanding of the usefulness of this type of study design for answering these types of questions.

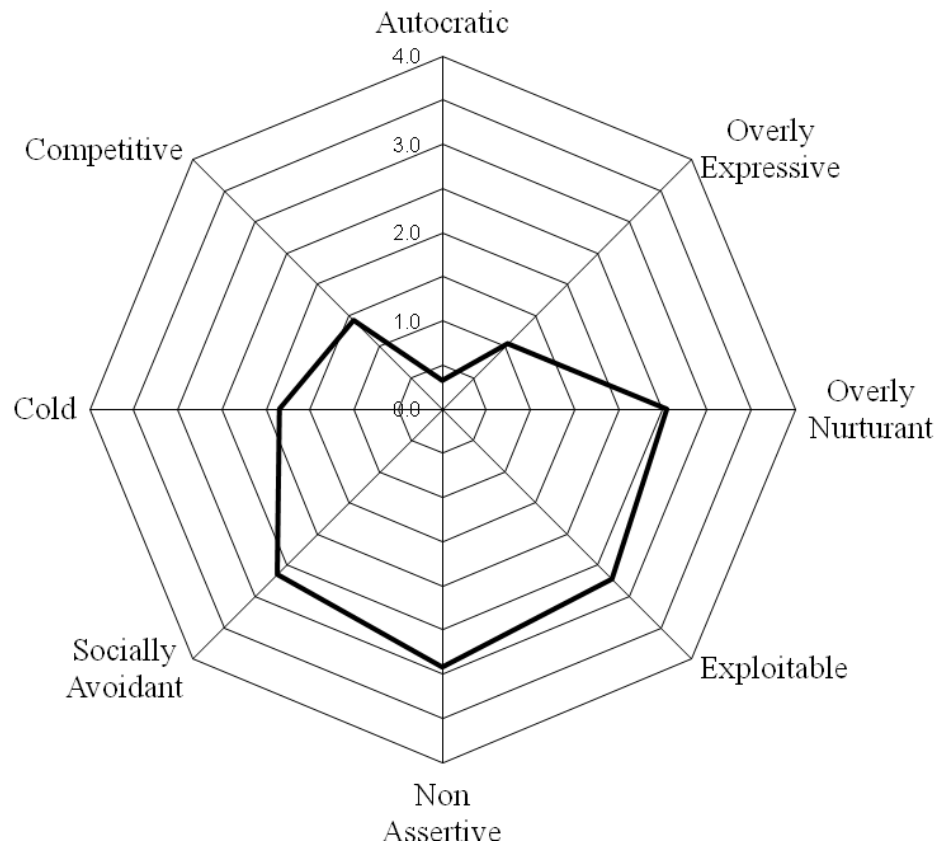
Most single case design studies are analysed using visual analysis techniques, which involve plotting data in a graph and assessing whether the outcome variable differs between baseline and treatment phases within individuals. However, in the last decade increasing attention has been paid to the analysis of this type of data using statistical methods such as effect size estimation, regression, randomised tests, and multilevel models. There is a growing evidence base for the use of multilevel modelling methods for analysing single cases (Moeyaert, Ferron, Beretvas, & Van den Noortgate, 2014; Shadish et al., 2013; Shadish, Zuur, & Sullivan, K.J., 2014; Van den Noortgate & Onghena, 2003). Some recent papers have presented evidence that Generalised Additive Models may provide some benefits over multilevel modelling using traditional general linear model (Shadish et al., 2014; Sullivan et al., 2015), especially for the analysis of single cases, where GAMs were found to provide more conservative parameter estimates. However the authors urge caution in their use and recommend traditional GLM analyses as a primary means of data analysis. In this

paper we therefore apply statistical analysis to the available data from all individuals within the current study, using general linear mixed models. We then fit models for each individual who has completed therapy, in order to provide a statistical summary of within-individual change. All analyses were performed using the “mgcv” package in R (Wood, 2010).

#### *4.4.2. Results*

##### *Description of sample*

A total of 13 participants agreed to take part in the study. Participants provided information at baseline including demographics, and history of depression. All participants were asked about the chronicity of their depression, the median response was 25 years or more. At baseline, 5 participants met criteria based on the HRSD for “very severe” depression (scores of 24 or above), 2 met criteria for “severe” depression (scores of 19-23), 2 for “moderate” depression (scores of 14-18), and 1 each for “mild” (scores of 8-13) and “normal” levels (scores below 8). Of the total sample, 4 participants were assigned to receive CBASP without DPI. There were no significant differences between individuals in the two conditions at baseline in symptom severity ( $t(9) = 1.00, p = 0.35$ ). Figure 1 presents IIP-32 scores for the whole sample at baseline, graphed onto the interpersonal circumplex.



**Figure 1.** Interpersonal profile of the sample at baseline.

#### *Modelling symptom change for the whole sample*

First, models were fitted using available data from all participants in the study. In order to test the study hypotheses, five models were compared. Model 1 evaluates only the effect of time, Model 2 evaluates only the effect of treatment (baseline and treatment are dummy coded as 0 and 1, respectively), Model 3 includes both time and treatment, along with an interaction for time\*treatment, and Model 4 extends Model 3 by controlling for the level 2 variable (participant). Model 5 includes a variable

controlling for intervention (CBASP vs CBASP without DPI), in order to provide a preliminary indication of any effect of intervention.

Results of the models are presented in Table 2, along with fit statistics. Model 1 revealed an overall significant effect of time, indicating a significant overall reduction in symptoms. There was also a significant effect of intervention in Model 2 ( $B = -3.70, p < .01$ ). When both terms, along with an interaction term, were included (Model 3), neither time or intervention remained significant. In this model the only significant term was the intercept. Goodness of fit statistics indicated that Model 3 was a substantial improvement over Model 2 ( $X^2(2) = 1095.1, p < .001$ ) but not Model 1 ( $X^2(2) = 52.28, p = 0.35$ ). Controlling for the effect of Participant (Model 4) did not improve model fit ( $X^2(1) = 0.04, p = 0.97$ ). However, controlling for the effect of intervention (Model 5) did provide a substantial improvement in model fit over Model 3 ( $X^2(1) = 101.75, p = 0.04$ ). In addition, in this model the effect of intervention was significant, indicating significant differences between participants in the two interventions in how they experienced change in CBASP.

**Table 2.** Coefficients with standard errors and fit statistics for the full sample and for the two completers.

	Model 1	Model 2	Model 3	Model 4	Model 5
<b>Full sample</b>					
Intercept	17.34 (0.71)***	15.84 (0.95)***	17.54 (1.27)***	17.52 (1.40)***	20.35 (1.85)***
Trend	-0.55 (0.07)***		-1.11 (0.63)	-1.11 (0.64)	-1.02 (0.63)
Treatment		-3.70 (1.15)**	0.72 (1.68)	0.72 (1.69)	1.31 (1.68)
Interaction			0.49 (0.64)	0.50 (0.65)	0.34 (0.64)
Participant				0.02 (0.004)***	
Condition					-2.13 (1.03)*
Treatment <i>p</i>		0.002	0.67	0.67	0.44
Residual deviance	2857.7 (116)	3900.5 (116)	2805.4 (114)	2805.4 (113)	2703.7 (113)
AIC	716.95	753.66	718.77	720.76	716.41
<b>Completers</b>					
Intercept	13.18 (0.99)***	11.63 (1.48)***	14.25 (2.07)***	10.23 (2.39)***	
Time	-0.35 (0.07)***		-1.75 (1.11)	-1.75 (1.03)	
Treatment		-2.93 (1.61)	-0.11 (2.50)	0.19 (2.32)	
Interaction			1.34 (1.11)	1.32 (1.03)	
Participant				2.68 (0.94)**	
Treatment <i>p</i>		0.08	0.10	0.94	
Residual deviance	574.69 (46)	769.27 (46)	539.37 (44)	453.95 (43)	
AIC	261.38	277.04	262.34	256.06	

Values in parentheses represent standard errors, except for Residual Deviance, where they represent degrees of freedom.

Significance: \*\*\* $p < .001$ ; \*\* $p < .01$ ; \* $p < .05$ .

It was possible that the significant differences observed between the two conditions might be explained by the fact that only two participants had completed treatment to date, and that these were both in the CBASP condition. Those in the non-DPI condition had incomplete data. We therefore repeated the analyses for only the two who had complete data. Summary statistics for this sample are provided separately in Table 2. Model 1 revealed an overall significant effect of time, indicating a significant overall reduction in symptoms. However, Model 2 revealed a non-significant effect of intervention, suggesting that there was no difference between the baseline and intervention phase for these two participants. When both terms, along with an interaction term, were included (Model 3), time was no longer significant. In this model the only significant term was the intercept. Goodness of fit statistics indicated that Model 3 was a substantial improvement over Model 2 ( $X^2(2) = 256.91$ ,

$p < .001$ ) but not Model 1 ( $X^2 (2) = 35.32, p = 0.24$ ). Adding the level 2 variable provided a significantly improved fit over this ( $X^2 (1) = 85.42, p = .004$ ). In addition, in this model the effect of participant was significant, indicating significant differences between participants in how they experienced change in CBASP. For both the full sample and the completer sample, participant effects appeared to account for more variance than either time or treatment. The following section therefore explores in more detail how change occurred within individuals who completed treatment.

#### *Within-participant treatment effects*

Two participants had completed treatment at the time of writing. They will be referred to as Case 1 and Case 2 in the following section. Case 1 was a 51 year-old female who reported a 37 year history of depression. She was not currently on any medication for depression, and had previously attended counselling for depression. Case 2 was a 38 year-old female who reported a 20 year history of depression. She was currently taking Fluoxetine and was also under review by a psychiatrist. She had previously had courses of CBT and counselling.

For each of these two participants, four models were tested (Table 3). Model 1 tested for the effect of time, Model 2 added a quadratic function to test for a curvilinear time trend, Model 3 tested for the effect of treatment versus baseline, and Model 4 tested for an interaction between time and treatment.

For Case 1 there was a significant effect of time in Model 1 ( $B = -0.39, p < 0.001$ ). Tests for a curvilinear trend did not provide a substantial improvement in model fit ( $X^2 (1) = 16.97, p = 0.15$ ), and the quadratic term was non-significant ( $B = 0.02, p = 0.17$ ), suggesting that the rate of change for this participant remained

constant. There was a significant effect of treatment ( $B = -4.84, p = 0.02$ ), but this effect was no longer significant when both time and treatment, along with the interaction term, were included. However, time remained significant ( $B = -2.60, p = 0.05$ ). For this participant there was no substantial improvement in fit between the null model (model 1) and either Model 2 (non-linear) or Model 4 (interaction) ( $X^2(2) = 25.55, p = 0.21$ ). Therefore, although this participant experienced a steady decrease in symptoms across the treatment, it may not have been due to the effects of the treatment.

**Table 3.** Summary statistics and model fit for each participant.

	Model 1	Model 2	Model 3	Model 4
<b>Case 1</b>				
Intercept	12.34 (1.18)***	14.01 (1.64)***	12.00 (1.75)***	15.90 (2.38)***
Trend	-0.39 (0.09)***	-0.87 (0.34)*		-2.60 (1.27)*
Treatment			-4.84 (1.93)*	-4.14 (2.91)
Interaction				2.25 (1.28)
Quadratic function		0.02 (0.02)		
Treatment p			0.02	0.17
Residual deviance	178.69 (21)	161.99 (20)	258.53 (21)	153.14 (19)
AIC	118.42	118.17	126.92	118.88
<b>Case 2</b>				
Intercept	14.28 (1.43)***	10.83 (1.82)***	11.25 (2.21)***	12.60 (2.94)***
Trend	-0.33 (0.10)**	0.57 (0.35)		-0.90 (1.57)
Treatment			-1.16 (2.42)	4.40 (3.52)
Interaction				0.41 (1.58)
Quadratic function		-0.04 (0.01)*		
Treatment p			0.64	0.22
Residual deviance	310.82 (23)	235.38 (22)	450.56 (23)	258.98 (21)
AIC	139.96	135.00	149.24	139.39

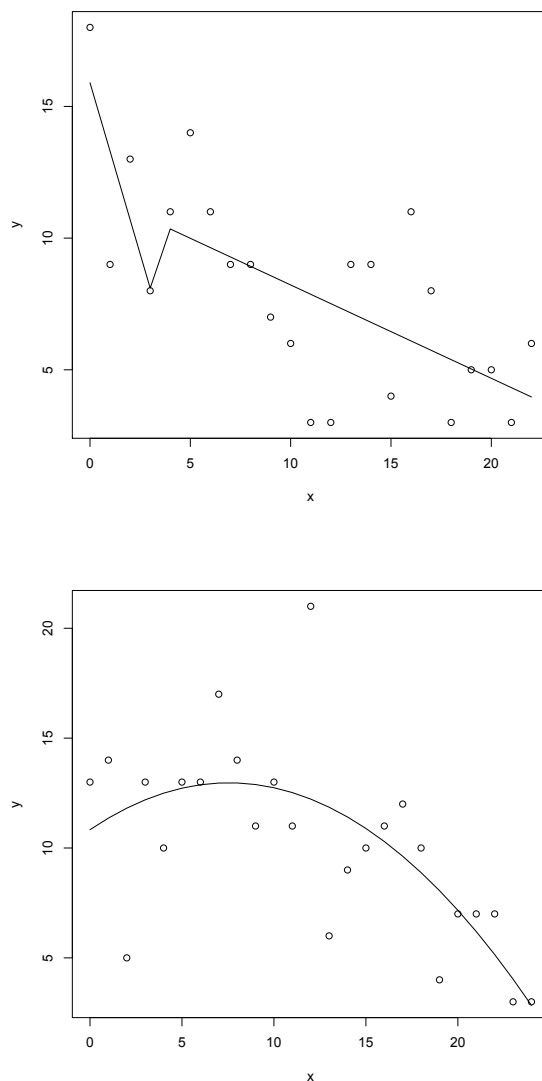
Values in parentheses represent standard errors, except for Residual Deviance, where they represent degrees of freedom.

Significance: \*\*\* $p < .001$ ; \*\* $p < .01$ ; \* $p < .05$ .

For Case 2, a significant effect of time was observed in Model 1. For this participant, Model 2 provided a substantially improved fit over Model 1 ( $X^2(1) = 75.44, p = 0.007$ ). The quadratic term was also significant in this model while the



linear term was not, suggesting that for this participant, change was non-linear. For this participant, the effect of treatment was found not to be significant, and there did not appear to be an interaction effect between time and treatment. Comparing the residual deviance of the models and AIC statistics would suggest that Model 2 provides the best fit for this participant (see Figure 2), which would suggest that the non-linear trend accounts for more of the variance than the effect of treatment compared with baseline.



**Figure 2.** PHQ-9 scores plotted against time for each case, with the trendline from Model 4 superimposed on data for Case 1, and the trendline from Model 2 superimposed for Case 2.

### *Visual analysis*

Each of the completing participants' PHQ-9 scores for every baseline assessment and every therapy session were plotted, along with PQ-SA and PQ-IDE scores (Figure 3). As is apparent in Figure 1, neither participant's baseline PHQ-9 scores were stable. For Case 1, from the start of the baseline period to the end of therapy there was a decrease from a score of 18 (Moderately severe depression) to a score of 6 (mild depression) at the end, representing a 66% decrease. This also met criteria for clinically significant change as recommended by McMillan, Gilbody and Richards (pre-treatment score of 10 or higher, post-treatment score of 9 or lower, and decrease of at least 5 points; 2010). Case 2 also showed clinically significant change (pre-score = 13, post-score = 3).

For both participants, achieving 'recovery level' functioning on PQ-SA and PQ-IDE appeared to precede a decrease in depression during the last 5 sessions of therapy. Both participants achieved and maintained this level of functioning by the final session, suggesting that learning in relation to the therapy goals had been achieved. Depression scores during the last 5 sessions remained relatively stable in the non-clinical range, which may indicate an effect of learning on symptoms. It is worth noting that for Case 2, the session 14 score for depression was very high which might explain the shape of the model fitted in Figure 2.

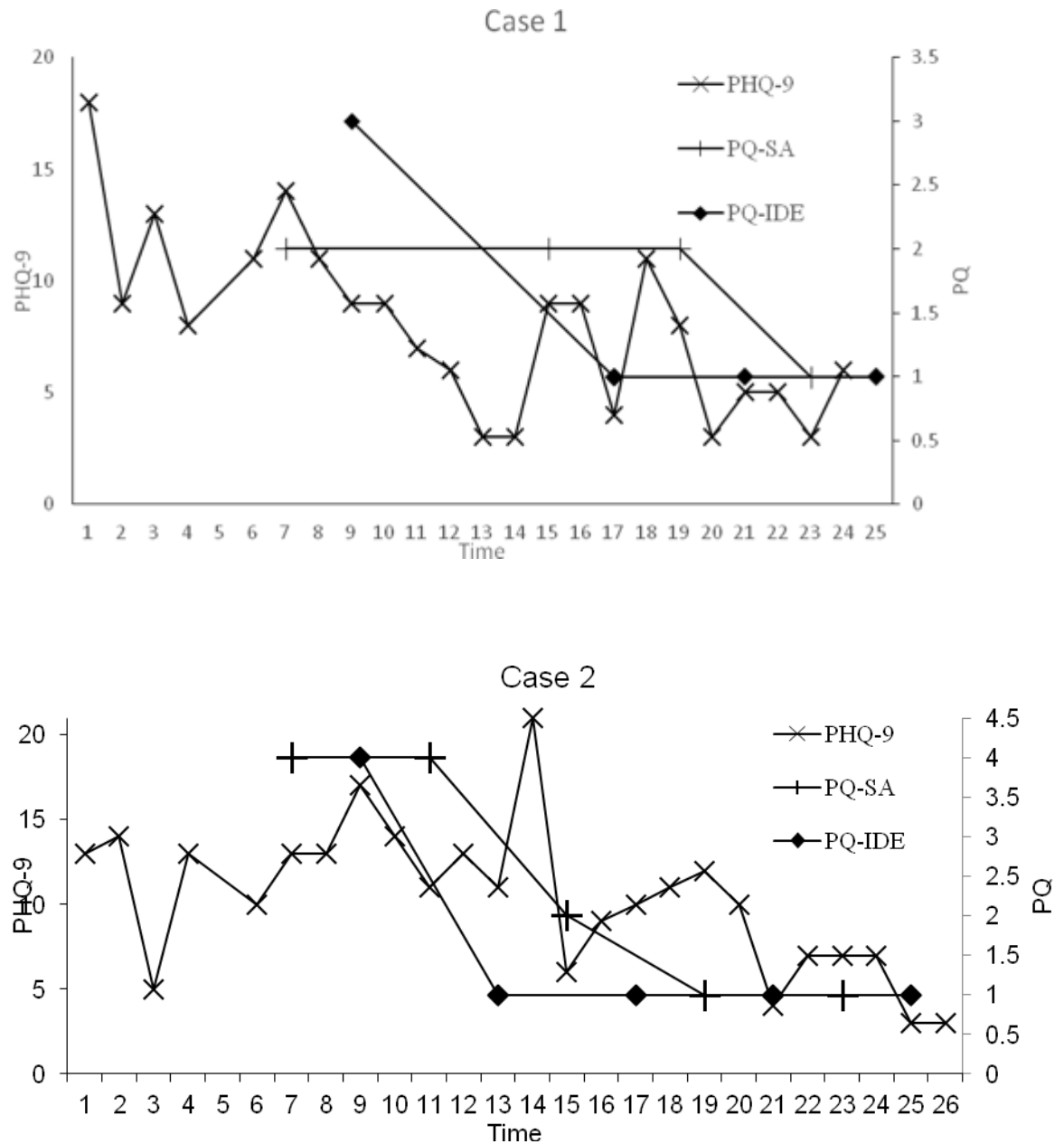
#### *4.4.3. Conclusions*

This study sought to extend the first study in this paper by investigating the process of change for a smaller number of individuals with more detailed within-participant data. The results for the whole sample are consistent with those from Study 1, with the level 2 variable appearing to account for the most variance in the model,

suggesting that participant differences play an important role in determining the process of change. By adding more time-points, it was hoped that the process of symptom change could be investigated in more detail within individual participants. The shape of change differed significantly between the two completers, with one experiencing linear change and the other appearing to follow a non-linear path, with larger gains occurring later in therapy. Visual inspection of participants' depression symptoms with their PQ-SA and PQ-IDE appeared to show that reaching recovery-level functioning on the two measures preceded a stabilising of symptom scores in the non-clinical range over the last few sessions of therapy.

#### **4.5. General discussion**

The aim of this paper was to investigate whether there is evidence for the hypothesised mechanism of change in CBASP. Based on McCullough's theory, individuals in CBASP would be expected to experience greater gains later in therapy as they gain skills in the two primary techniques – Situational Analysis and the Interpersonal Discrimination Exercise. Further, we expected that achieving recovery-level functioning on measures of learning acquisition would precede symptom improvements. Two studies were presented to test these hypotheses: the first presented an analysis of an existing dataset from a recent CBASP case series, with the aim of determining whether there was evidence for the predicted, non-linear pattern of change. This study further sought to explore the impact of acquisition learning and interpersonal style on symptom change. The second study used a single-case, multiple baseline design to investigate in more detail the patterns of change within individuals receiving CBASP. This second study also sought to investigate the utility of recently suggested methods of analysing single case data using multilevel models.



**Figure 3.** Participants' ratings of depression and situational analysis and interpersonal discrimination exercise learning from baseline to end of treatment.

The findings of the studies presented in this paper are mixed. The analyses in Study 1 suggest that SA learning is a more important predictor of symptom improvement than IDE, and that a hostile-submissive interpersonal style is associated generally with higher levels of depression, but does not affect an individual's

likelihood to experience change in CBASP. There was limited evidence for a non-linear pattern of change, with this only observed for a single case in Study 2. Overall it appears likely that individuals experience change gradually and relatively steadily in CBASP. The analyses in Study 2 revealed limited evidence for the effect of the intervention, as the intervention term was non-significant when controlling for individual differences between participants. This was consistent with Study 1, which found significant variance in slopes across participants, and together these findings suggest that individuals' experiences of change in CBASP vary. The designs of the two studies in the current paper did not allow for an exploration of between-subjects variables that might account for these differences.

Study 2 also had a secondary aim of evaluating the usefulness of multilevel modelling techniques for statistically evaluating treatment effects for single cases. The findings point to a number of possible advantages of using this analysis method over visual analysis or simple effect size calculation. None of our analyses revealed a significant effect of treatment when compared with baseline, whereas visual analysis of the data would likely have led to the conclusion that there was an effect of treatment. Further, results from the analyses of the two completers would suggest that there is insufficient data to conclude a significant effect of therapy, despite both meeting criteria for reliable change on the PHQ-9. It is worth noting that neither participant achieved a stable baseline, which may have affected results. A less time-limited study with a longer baseline period may provide a better indication of these effects. One limitation of the use of a single-case design is that the sample size precludes adding level 2 (between-participant) variables. This is especially important given that, as in Study 1, participant differences appeared to account for the most variance in the

models. Study 1 found evidence that baseline levels of distress were not significantly associated with the rate of symptom change. This is a potentially important finding as it may provide some evidence that observed symptom improvement was not due to natural recovery or regression to the mean.

#### *4.5.1. Implications for theory*

These results have a number of potential theoretical implications. The finding in Study 1 that SA learning appears to be more important than IDE learning is potentially important and merits further research attention. In CBASP, the IDE is used to help patients to learn to discriminate between the way maltreating significant others made them feel and behave and how the clinician reacts to them. McCullough (2006) suggests that the best treatment outcomes occur when patients move from responding to their therapists negatively as they would to their maltreating significant others, and begin responding more positively to the clinician. Whereas SA is repeated throughout treatment and is completed as homework between sessions, the IDE is used by the therapist as and when the situation arises. There may therefore be a good deal of variation between therapists and between patients in the extent to which the IDE is used, whereas SAs form the bulk of work for all patients. Study 2 attempted to explore this further by including a condition where the IDE was not utilised, but the limited available data precluded any investigation of any effects. Based on our findings it would appear that SA may be the more important component.

McCullough describes the interpersonal styles of chronically depressed individuals as predominantly hostile and submissive (McCullough, 2000). Study 1 did find an association between this interpersonal style and depression symptoms, as was

expected. However the results suggested that hostile-submissiveness did not lead to significant differences in symptom improvement. This is a potentially important finding given that individuals with this interpersonal style could be expected to be difficult to engage in treatment (Constantino et al., 2008; McCullough, 2000). This finding is consistent with previous research that found that individuals high in hostile-submissiveness early in CBASP displayed reductions in hostile-submissive behaviours and increases in friendly and friendly-dominant measures by the end of therapy (Constantino et al., 2008). Together these findings appear to provide support for the hypothesised mechanism of change in CBASP. It is also consistent with other models, such as Mentalisation Based Therapy (Allen & Fonagy, 2006), where a lack of mentalising could explain a hostile-submissive interpersonal style, and as mentalisation increases individuals might begin to experience more meaningful relationships, leading to a more friendly interpersonal style.

#### *4.5.2. Research implications*

The results of the current studies bring up a number of questions for future research. Firstly, in order to fully understand the mechanism of change in CBASP, the differential roles of Situational Analysis and the interpersonal components will need to be investigated further. Study 1 found SA learning to be the only significant predictor of symptom change, but including IDE learning in the model improved fit, suggesting that it may play a role. Study 2 attempted to evaluate this differential effect through the use of a no-disciplined personal involvement condition, but had insufficient data to perform a comparison. This will need to be further tested with complete data.

A second important question for future research is about between-participant factors that affect symptom change. In both studies, significant differences between participants appeared to account for substantial variance in the models. It will be important to determine what factors might account for these differences. There is evidence, for example, that therapist effects have a significant impact on outcome of CBT for individuals with panic disorder, and there is evidence that factors such as poor social support are associated with relapse in individuals with treatment resistant depression (Fekadu et al., 2012). Therapist adherence and patient facilitation of adherence have been found to predict session-by-session change in cognitive therapy for depression (Strunk, Brotman, & DeRubeis, 2010). Controlling for therapist effects and investigating the role of the therapeutic alliance would therefore appear to provide a logical next step in evaluating predictors of change.

#### *4.5.3. Strengths and limitations*

The analyses presented in this paper had a number of strengths. The statistical methods allowed for a detailed analysis of within-participant change in CBASP across both samples. This is the first time that this has been investigated, and provides some evidence for the theoretical assumptions on which CBASP is based. Firstly, the significant impact of SA functioning on symptom levels found in Study 1 provides support for McCullough's hypothesis that therapeutic gains are brought about through helping patients to engage with the consequences of their behaviour and addressing dysfunctional interpersonal strategies. Visual analysis of the completers' data in Study 2 also appeared to support this, with both participants' depression scores remaining in the normal and mild depression range once recovery level functioning on SA had been



achieved. Study 1 also found that as predicted by McCullough (2000), hostile-submissiveness was associated with higher symptom levels, but that it did not have a significant impact on change during therapy, suggesting that those individuals were no less likely to engage in CBASP.

The method of analysis used in Study 2 provided some apparent advantages over traditional methods of analysing single-case studies. Visual analysis of the data for both participants, and application of recommended criteria for clinically significant change appeared to support a significant treatment effect for both participants. However, the models did not support this, suggesting that the significant change over time might have been explained by factors other than treatment. This is consistent with previous research where statistical models have been applied to single-case studies previously analysed using visual analysis, where authors have found more nuanced effects for multilevel models than visual analysis (Sullivan et al., 2015).

The results presented in this paper should be considered in the context of its limitations. Study 1 applied analyses to a dataset from a case series designed primarily to evaluate therapeutic outcomes by comparing end of therapy symptoms with pre-therapy symptom levels. The BDI-II data gathered during therapy was therefore only collected for a limited number of time-points, which placed limitations on the analyses in this paper. Outcome was assessed at every 5<sup>th</sup> session, meaning that our analysis may have missed subtle trends occurring between measurement points. In addition, this study did not include any baseline measurements or control conditions, which makes it difficult to discern between the effects of the intervention and potential effects of natural recovery or regression to the mean. However, our method of analysis may provide some advantages in this respect over simply considering pre-post therapy

change, as we were able to test for effects of initial symptom severity on change over time. That no effect was found provides some evidence against the effect of regression to the mean.

Study 2 was designed as a single-case design. At the time of writing only 2 participants had completed therapy, and both were CBASP participants, meaning we could not test the hypothesis about those not receiving IDE. In addition, the analysis of single-case designs using multilevel modelling is a relatively recent area of research (Shadish et al., 2013; Sullivan et al., 2015; Van den Noortgate & Onghena, 2003). There are currently no clear indications in the literature about requisite sample sizes, especially given that the majority of authors focus on detecting between-subjects effects, whereas in the current study we sought primarily to model within-subject effects (Shadish et al., 2013). Muller, Edwards, Simpson and Taylor (2007) demonstrated a tendency for inflated type 1 error in mixed models in small samples, although the current analyses did not reveal significant treatment effects. From our analyses it would seem likely that adding further time-points to the baseline period would improve model fit and power, given that participants did not achieve stable baselines. The lack of clarity about what constitutes adequate sample size for single case data therefore needs further evaluation.

The number of baseline assessments in Study 2 was relatively low, and was determined by feasibility rather than being randomised. All participants completed at least 3 baseline assessments, though some completed additional assessments if there was a delay in beginning therapy. A recent study of schema therapy for chronic depression included a baseline phase that lasted between 6 and 24 weeks, and found a tendency for an initial improvement in symptoms over the baseline, before symptom

levels became stable (Renner, Arntz, Peeters, Lobbestael, & Huibers, 2016). The small number of baseline assessments in the current study might therefore have prevented us from achieving stable baselines for participants, which may explain the non-significant treatment effects in our models.

As mentioned above, the analysis of single-case data using multilevel modelling is a relatively new area. Simulation studies using existing single-case data suggest that the approach can provide reliable estimates of effects, but this has not yet been fully explored empirically. The analyses in this paper provide some support that this approach can provide a useful addition to visual analysis. However, one limitation of the analyses was that the study design prevented an exploration of between-subject effects.

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## 5. Appendices

### Appendix A. Quality rating sheet for meta-analysis.

#### Quality Assessment

##### **Representativeness**

1. What kind of recruitment strategy has been used?

Randomised/consecutive (2) Non-randomised/convenience (0) Not stated (0)

##### **Sample Size**

2. How was the sample size calculated?

Not reported (0) Power calculation reported (1) Power calculation  
reported; sample size deviated by  $\leq 10\%$  (2)

3. What was the total sample size?

25 – 129 (0) 130 – 499 (1) 500+ (2)

##### **Participation rate**

4. Is the participation rate  $> 75\%$ ?

Yes (2) No (0) Not reported (0)

##### **Criteria for Depression**

5. How has depression been detected?

Clinical interview (2) Screening tool only (0)

##### **Measurement of Hostility, Submissiveness, Hostile-submissiveness constructs**

6. Was interpersonal style measured using validated measures?

Yes (1) No (0)

##### **Eligibility Criteria**

7. Have eligibility criteria been specified?

Yes (1) No (0)

**Total =     /12**

**Appendix B.** Letter of invitation to potential participants.

**Letter of invitation to participate in a study entitled “Does disciplined personal involvement precede change in CBASP?”**

**Version 1, 28 November, 2014**

Dear \_\_\_\_\_,

We are aware that you are currently waiting to be seen for psychological therapy and would like to invite you to participate in a study evaluating a form of therapy called Cognitive Behavioural Analysis System of Psychotherapy (CBASP) which is taking place within the service in conjunction with The University of Edinburgh.

CBASP is a form of therapy that has been designed specifically for treating severe and chronic depression. If you decide to take part you will be offered this therapy. The study will involve meeting with the researcher three times to fill in some questionnaires, and then beginning therapy. All participants in the study will be offered up to 20 sessions of therapy over a period of six months. If you do decide to take part in the study and you meet all of the criteria for taking part, you would be able to begin therapy within the next month.

Included with this letter are some documents to give you more information about the study and what participation would involve.

Participation in this study is entirely voluntary. Participants are free to end their participation at any time.

If you have any questions regarding this study, or would like additional information to assist you in reaching a decision about participation, please contact the department using the contact details provided.

If you feel you have received enough information about the study and would like to take part, please contact the department to arrange your first session.

Yours Sincerely,

## **Appendix C. Participant Information Sheet**

### **PARTICIPANT INFORMATION SHEET**

**Version 2, 9<sup>th</sup> March, 2015**

#### **What is the process of change in Cognitive Behavioural Analysis System of Psychotherapy (CBASP)?**

This information sheet explains a research study taking place in NHS Lothian and Tayside. We are inviting individuals suffering from depression who have been referred to see a psychological therapist for help with their problem. We are evaluating a form of therapy that is offered by your service called Cognitive Behaviour Analysis System of Psychotherapy (CBASP). Studies have shown that CBASP can help people who have long-standing depression to improve their symptoms and is currently offered routinely by this service. If you decide to take part you will receive CBASP with one of the service's trained therapists. Before you decide whether or not to participate, it is important that you understand why the research is being done and what it will involve. Please read this leaflet and discuss with others if you wish. If there is anything that you are still unclear about, please contact us for further information. Contact details are at the end of the leaflet.

#### **What is CBASP?**

CBASP is a form of therapy specifically designed to treat individuals with chronic depression (depression lasting for more than 2 years). In CBASP the aim is to help you understand your thinking patterns and how what we think and do can affect the outcomes of different situations. Ultimately the therapy will help you to realise unhelpful thinking patterns and to challenge these thoughts.

#### **Why are we conducting the research study?**

CBASP has been found to be effective for helping people suffering with chronic depression in several large studies. We are conducting this study to try to understand what it is about the therapy that makes it work. We will do this by taking measurements of depression (using a questionnaire) at every therapy session so that we can look at how this changes over the course of therapy. We hope that this can help us to understand what parts of the therapy are particularly useful. The results of the study could then be used to inform how therapy should be provided in the future to make sure it gets the best results.

#### **Do I have to take part?**

No, taking part in this study is completely voluntary. It is up to you whether or not to take part. You will be given at least seven days to decide whether or not you would like to take part. Even if you decide to take part you are still free to leave the study at any time and you do not have to give a reason. Whether or not you decide to take part in the study, or leave the study, will not in any way influence the care you receive.

#### **Who is carrying out the research?**

This project is led by Dr Timothy Bird, a trainee clinical psychologist at the University of Edinburgh and NHS Lothian, who is supervised by Professor Matthias Schwannauer (University of Edinburgh) and Dr Massimo Tarsia (NHS Lothian), who are both Clinical Psychologists. The therapy in the study will be provided by trained clinicians in your local service who provide CBASP routinely to clients with long-standing depression, and Timothy Bird will meet with you for your three assessment appointments before the start of therapy.

### **What does participating in the research involve?**

As part of the study, you will be asked to complete some questionnaires at each therapy session to measure your depression. As part of the study you would also be asked to complete a questionnaire 3 times (once a week for three weeks) before starting therapy. There will also be a follow-up questionnaire approximately 6 weeks after the end of therapy which will be posted to you. The questionnaires will not take any longer to complete than those that are routinely used by your service.

- i) If you agree to participate we will ask your permission for the CBASP sessions to be audio recorded so that other trained therapists can rate what the therapist working with you does. However, you will still be able to participate in the study if you do not want your therapy sessions recorded.
- ii) If you agree to participate, you will be asked to complete a number of questionnaires at three weekly appointments before starting treatment. At the first appointment these will take about 20 minutes to complete. After that you will only have to complete one questionnaire each time which should take less than 5 minutes. Then at each therapy session you will be asked to complete one of these questionnaires which should again only take 5 minutes. You will then be asked to complete all of the questionnaires again 6 weeks after the end of your therapy.
- iii) We will ask that if you change your address during the study that you let us have your new contact details so that we can send you the follow-up questionnaires.
- iv) Studies have shown that CBASP works best when people attend 20 one-hour sessions on a weekly basis. In this study we will offer you up to 20 sessions over a six-month period, which is what you would normally be offered by the service. You will be asked to attend therapy sessions in a clinic on a weekly basis. It is important that you consider this commitment before deciding to take part.
- v) Participants who decide to participate will receive one of two slightly different forms of CBASP. In CBASP, one of the exercises you will do along with your therapist is looking at some of your past relationships and how they might have affected you. In this study half of participants will be offered a form of CBASP where the therapist uses your relationship with him or her as a way of demonstrating some of the effects that previous relationships might have had. For the other half of participants the therapist will not focus on their relationship with you but will instead pick another important relationship in your life to discuss. Which of these you receive will be randomly decided when you decide to participate.

**Attending therapy sessions**

- If you would like to receive the service's regular treatment and do not wish to take part in this research, you do not need to do anything. You will remain on the service's waiting list until a member of the service's team contacts you to discuss treatment options.
- If you agree to take part in this research, you will be contacted by the researcher and offered an appointment to attend an initial session to complete questionnaires. You will also have the opportunity to ask questions about the study at this time.
- You will then be asked to meet with the researcher two more times before beginning therapy with one of the study therapists.

**Ending treatment**

Participants the study will be free to withdraw from the study at any time by contacting Timothy Bird (see contact details below). If you wish you may also ask for your data and any audio recordings to be destroyed. Unless you contact us to tell us otherwise, if you have attended your first appointment and signed the consent form we will consider you to be participating in the study until the end of the 6 months. We will then send you the subsequent follow-up questionnaires unless you tell us otherwise.

**Information about you will be kept strictly confidential**

Whichever form of CBASP you receive, clinical notes about your contact with the therapist and all questionnaires will be stored confidentially at the service base. All questionnaires related to the research will NOT have your name or personal details on and will be stored in a secured office in a locked filing cabinet. Each participant will be given a unique participant identification number which will be included on their questionnaires.

The results of the research project will be written in a report; however the personal details of any person who has participated in the research will not be given. Your personal information will only be available to people involved in doing the research project and staff at the university who are responsible for monitoring the research, in addition to professionals in the service where you receive your therapy. Your GP will be kept informed of your participation in this study and of your progress through therapy.

If you consent to having your CBASP sessions audio recorded, these will be kept for until the end of the study. These recordings will be kept confidentially and securely on secure NHS servers and accessed only by members of the research team. Audio recordings will be transcribed and therefore anonymized, after which recordings will be deleted.

If you tell your therapist anything that makes them think that you or anyone else might be at risk of serious harm, your therapist will discuss this immediately with a senior member of the service if they feel this risk is urgent. This information may be passed on to a specialist team who can assess the situation in more detail. Your GP will also be kept updated. If your therapist is made aware of any concern about the

wellbeing of a child or vulnerable adult then they have to share this information with social services.

**Are there any potential benefits of participating in the research?**

There will be no direct benefits to you by taking part in the study.

**Are there any potential risks of participating in the research?**

As with all therapy, some people may find talking about their emotions and experiences in therapy upsetting. However, the risk of this will be no greater than when receiving any other form of therapy. All therapists are trained in supporting people who are distressed.

**What if something goes wrong?**

If you have any further questions about the study please contact Timothy Bird on: (0131 537 6169) [timothy.bird@nhslothian.scot.nhs.uk](mailto:timothy.bird@nhslothian.scot.nhs.uk), or Professor Matthias Schwannauer (0131 651 3954) or email [m.schwannauer@ed.ac.uk](mailto:m.schwannauer@ed.ac.uk). If you would like to discuss this study with someone independent of the research team please contact 0131 536 8981. If you have any concerns about participating in the research, please discuss this with a member of the research team in the first instance if you feel able to. If you wish to make a complaint about the study please contact NHS Lothian:

NHS Lothian Complaints Team  
2nd Floor  
Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG  
Tel: 0131 465 5708  
Email: [craft@nhslothian.scot.nhs.uk](mailto:craft@nhslothian.scot.nhs.uk)

NHS Tayside:

Complaints and Feedback Team  
Ninewells Hospital  
Dundee  
DD1 9SY  
Telephone: 0800 027 5507  
Email: [feedback.tayside@nhs.net](mailto:feedback.tayside@nhs.net)

**This study has been reviewed by an NHS Ethics Committee and approved by research and development at NHS Lothian and NHS Tayside.**

**Decisions to make....**

If you would like to participate in the research then you can contact the service to inform them using the contact details provided. You will then be contacted and offered an appointment to meet with the researcher to fill in the baseline questionnaires.

Thank you very much for reading this information sheet, if you have any further questions please contact Timothy Bird, the lead researcher or his academic supervisor Matthias Schwannauer using the details provided above.

**Consent Form**  
**Version 2, 9<sup>th</sup> March, 2015**

**What is the process of change in Cognitive Behavioural Analysis System of Psychotherapy (CBASP)?**

**Chief Investigator:** Timothy Bird

**Participant Number:**.....

This consent form is for people who are attending Cognitive Behavioural Analysis System of Psychotherapy (CBASP) sessions in the research study entitled "What is the process of change in Cognitive Behavioural Analysis System of Psychotherapy (CBASP)?". The project is being sponsored by the University of Edinburgh.

Please read the information sheet before you complete this consent form.  
Please consider each of the following statements.

Please initial box

1. I confirm that I have read, understand and agree to the information provided in the information sheet dated ..... (version ..... ) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

☐

3. I give consent for researchers to share information about my participation in this study and my progress in therapy with my GP.

☐

4. I understand that quotes and scores from questionnaires may be part of the final research report and used in research publications, but under no circumstances will names or identifying characteristics be included.

☐

5. I give my consent for some of my therapy sessions to be audio recorded and shared with other members of the research team in order to rate the quality of therapy being delivered.

Yes / No  
(please circle one)

6. I give consent for the researchers to contact me (either by telephone or in writing) to ask me if I wish to return for further therapy sessions.

☐

7. I give consent to the researchers to post packs of questionnaires out to my home address six weeks after I have finished receiving the study intervention.

☐



8. In the unlikely event that I lose capacity to give consent throughout my time in therapy, I give permission for the researchers to continue to use audio recordings and information from questionnaires collected up until that time. I understand that no further information would be collected from me if it was deemed that I do not have capacity to continue participating in the study.

Yes / No  
(please circle one)

9. I give consent for the audio recordings of my therapy sessions and information from my questionnaires to be kept confidentially for up to 10 years after the study has finished (until May 2025) in order that the information can be used in future ethically approved research studies.

☐

10. I understand that sections of the data collected during the study, may be looked at by individuals from The University of Edinburgh, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data.

☐

11. I agree to take part in the above study.

☐

I would be grateful if you would sign this form to show that you have read, or have had read to you the contents of this information sheet and that you consent to take part in the study.

_____	_____	_____
Name of participant	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

If you have any further questions about the research please contact Timothy Bird who is the lead researcher on the project and can be contacted using the details above.

**Appendix E.** Confirmation of ethical approval and of approval of substantial amendment.

**WoSRES**  
*West of Scotland Research Ethics Service*



**West of Scotland REC 5**

Ground Floor - Tennent Building  
Western Infirmary  
38 Church Street  
Glasgow  
G11 6NT

Dr Timothy Bird  
Department of Psychology, Royal Edinburgh  
Hospital  
Morningside Place  
Edinburgh  
EH10 5HF

Date 09 March 2015

Direct line 0141 211 2482  
Fax 0141 211 1847  
E-mail WoSREC5@ggc.scot.nhs.uk

Dear Dr Bird

**Study title:** How is psychological change experienced by individuals receiving Cognitive Behaviour Analysis System of Psychotherapy (CBASP) and how is this affected by Disciplined Personal Involvement? A multiple baseline single-case design

**REC reference:** 15/WS/0027

**IRAS project ID:** 165874

Thank you for your e-mail of 9 March 2015. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 24 February 2015

**Documents received**

The documents received were as follows:

Document	Version	Date
Participant consent form	2	09 March 2015
Participant information sheet (PIS)	2	09 March 2015

**Approved documents**

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors)		08 August 2014

only)		
GP/consultant information sheets or letters	1	28 November 2014
Letter from sponsor		16 June 2014
Letters of invitation to participant	1	28 November 2014
Non-validated questionnaire	1	28 November 2014
Participant consent form	2	09 March 2015
Participant information sheet (PIS)	2	09 March 2015
REC Application Form [REC_Form_28012015]		28 January 2015
Research protocol or project proposal	1	04 December 2014
Summary CV for Chief Investigator (CI)		
Summary CV for supervisor (student research)		
Validated questionnaire [IIP-32]		
Validated questionnaire [BDI-II]		
Validated questionnaire [PQ-IDE]		
Validated questionnaire [PQ-SA]		
Validated questionnaire [Sad-IDE]		
Validated questionnaire [WAI-Client]		
Validated questionnaire [WAI-Therapist]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/WS/0027	Please quote this number on all correspondence
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Yours sincerely



**Rose Gallacher**  
Assistant Administrator

Copy to: *Ms Jo-Anne Robertson*  
*Karen Haggart, NHS Lothian*

Dr Timothy Bird  
Department of Psychology  
Royal Edinburgh Hospital  
Morningside Place  
Edinburgh  
EH10 5HF

**West of Scotland REC 5**  
Ground Floor - Tennent Building  
Western Infirmary  
38 Church Street  
Glasgow  
G11 6NT

Date 19 May 2015  
Direct line 0141 211 2102  
E-mail WoSREC5@ggc.scot.nhs.uk

Dear Dr Bird

**Study title:** How is psychological change experienced by individuals receiving Cognitive Behaviour Analysis System of Psychotherapy (CBASP) and how is this affected by Disciplined Personal Involvement? A multiple baseline single-case design  
**REC reference:** 15/WS/0027  
**Amendment number:** 1  
**Amendment date:** 27 April 2015  
**IRAS project ID:** 165874

**Summary of amendment:** Change of validated questionnaires: Use of Patient Health Questionnaire-9 and Hamilton Rating Scale for Depression 21-item instead of the Beck Depression Inventory-II

The above amendment was reviewed by the Sub-Committee in correspondence.

#### **Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### **Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	1	27 April 2015
Research protocol or project proposal	2	13 May 2015
Validated questionnaire [PHQ-9]		
Validated questionnaire [HAM-D]		

#### **Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

## **R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

## **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/WS/0027:	Please quote this number on all correspondence
-------------	--

Yours sincerely



for  
**Dr Stewart Campbell**  
Chair

Enclosures:                      List of names and professions of members who took part in the review

Copy to:                          Karen Haggart, NHS Lothian  
   Ms Jo-Anne Robertson, University of Edinburgh

## Appendix F. R&D Approval for NHS Lothian and NHS Tayside.

### University Hospitals Division



Queen's Medical Research Institute  
47 Little France Crescent, Edinburgh, EH16 4TJ

DY/LM/approval

08 May 2015

Dr Massimo Tarsia  
East & Midlothian Psychological Therapies Service  
Primary Care Centre  
35-37 High Street  
Bonnyrigg  
EH19 2DA

Research & Development  
Room E1.12  
Tel: 0131 242 3330

Email:  
R&DOffice@nhslothian.scot.nhs.uk

Director: Professor David E Newby

Dear Dr Tarsia

**Lothian R&D Project No:** 2015/0220

**Title of Research:** How is psychological change experienced by individuals receiving Cognitive Behaviour Analysis System of Psychotherapy (CBASP) and how is this affected by Disciplined Personal Involvement? A multiple baseline single-case design

**REC No:** 15/WS/0027

**Participant Information Sheet:**  
Version 2 dated 9 March 2015

**Consent Form:**  
Version 2 dated 9 March 2015

**Protocol:** Version 1 dated 4 December 2014

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

A handwritten signature in black ink, appearing to be 'D Young'.

Dr Douglas Young  
Principal R&D Manager

CC: Dr Timothy Bird, Chief Investigator, Royal Edinburgh Hospital  
Dr Patricia Graham, Head of Adult Mental Health Psychology Services, NHS Lothian

09 December 2015

Mr Robert MacVicar  
Clinical Nurse Consultant  
Advanced Interventions Service  
Level 6, South Block  
Ninewells Hospital and Medical School  
Dundee  
Scotland  
DD1 9SY

Dear Mr MacVicar,

**R&D MANAGEMENT APPROVAL – TAYSIDE**

**Title:** How is psychological change experienced by individuals receiving Cognitive Behaviour Analysis System of Psychotherapy (CBASP) and how is this affected by Disciplined Personal Involvement? A multiple baseline single-case design

**Chief Investigator:** Dr Timothy Bird

**Principal Investigator/Local Collaborator:** Mr Robert MacVicar

**Tayside Ref:** 2015MH05      **NRS Ref:** NRS15/MH151

**REC Ref:** 15/WS/0027

**Sponsor:** University of Edinburgh and NHS Lothian

**Funder:** Student project – no funding

Many thanks for your application to carry out the above project here in NHS Tayside. I am pleased to confirm that the project documentation (as outlined below) has been reviewed, registered and Management Approval has been granted for the study to proceed locally in Tayside.

Approval is granted on the following conditions:-

- ALL Research must be carried out in compliance with the Research Governance Framework for Health & Community Care, Health & Safety Regulations, data protection principles, statutory legislation and in accordance with Good Clinical Practice (GCP).
- All amendments to be notified to TASC R&D Office via the correct amendment pathway. Either direct to the R&D Office or via the Lead Co-ordinating Centre depending on how the study is set up (<http://www.hra.nhs.uk/nhshsc-rd-uk-process-management-amendments/>).
- All local researchers must hold either a Substantive Contract, Honorary Research Contract, Honorary Clinical Contract or Letter of Access with NHS Tayside where required (<http://www.nihr.ac.uk/policy-and-standards/research-passports.htm>).
- TASC R&D Office to be informed of change in Principal Investigator, Chief Investigator or any additional research personnel locally.
- Notification to TASC R&D Office of any change in funding.



- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until destruction of this data.
- All eligible and adopted studies will be added to the UKCRN Portfolio database <http://public.ukcrn.org.uk/>. Recruitment figures for eligible and adopted studies must be recorded onto the Portfolio every month. This is the responsibility of the lead UK site. If you are the lead, or only UK site, we can provide help or advice with this. For information, contact Sarah Kennedy (01382 383882 or [sarah.kennedy17@nhs.net](mailto:sarah.kennedy17@nhs.net)) or Margaret Marshall (01382 383091 or [margaret.marshall7@nhs.net](mailto:margaret.marshall7@nhs.net)).
- Annual reports are required to be submitted to TASC R&D Office with the first report due 12 months from date of issue of this management approval letter and at yearly intervals until completion of the study.
- Notification of early termination within 15 days or End of Trial within 90 days followed by End of Trial Report within 1 year to TASC R&D Office.
- You may be required to assist with and provide information in regard to audit and monitoring of study.

Please note you are required to adhere to the conditions, if not, NHS management approval may be withdrawn for the study.

#### Approved Documents

Document	Version	Date
REC – Provisional Favourable Ethical Opinion Letter		24 February 2015
REC – Favourable Ethical Opinion Letter		09 March 2015
REC – Favourable Ethical Opinion of Amendment Letter (AM01 dated 27/04/2015)		19 May 2015
NHS R&D form		18 February 2015
NHS SSI form		06 November 2015
Insurance Certificate		08 August 2014
CV [Dr Timothy Bird]		
CV [Robert MacVicar]		
Letter of Access [Dr Timothy Bird]		09 December 2015
Protocol	2	13 May 2015
Participant Information Sheet (PIS)	2	09 March 2015
Consent Form	2	09 March 2015
GP Letter	1	28 November 2014
Letter of Invitation to Participate	1	28 November 2014
Questionnaire [Participant Demographic Questionnaire]	1	28 November 2014
Other [Hamilton Depression Rating Scale (HAM-D)]	1	12 May 2015
Questionnaire [Patient Health Questionnaire – 9 (PHQ-9)]	1	12 May 2015

May I take this opportunity to wish you every success with your project.

Please do not hesitate to contact TASC R&D Office should you require further assistance.



Yours sincerely



Elizabeth Coote  
Head of Non-Commercial Research Services

Tayside medical Science Centre (TASC)  
Ninewells Hospital & Medical School  
TASC Research & Development Office  
Residency Block, Level 3  
George Pirie Way  
Dundee DD1 9SY  
Email: [liz.coote@nhs.net](mailto:liz.coote@nhs.net)  
Tel: 01382 383876 Fax: 01382 740122

c.c. Dr Timothy Bird  
Margaret Marshall, Local UKCRN Portfolio Representative  
TASC Feasibility Team

## Appendix G. Letter of access for NHS Tayside.



EC/LS

09 December 2015

Dr Timothy Bird  
Trainee Clinical Psychologist  
NHS Lothian  
Royal Edinburgh Hospital  
Morningside Terrace  
Edinburgh  
EH10 5HF

Dear Dr Bird,

### Letter of Access for Research

**Tayside R&D Project ID: 2015MH05**

**NRS Ref: NRS15/MH151**

**Title: How is psychological change experienced by individuals receiving Cognitive Behaviour Analysis System of Psychotherapy (CBASP) and how is this affected by Disciplined Personal Involvement? A multiple baseline single-case design**

**REC Ref: 15/WS/0027**

**Funder: Student project – no funding**

**Sponsors: University of Edinburgh and NHS Lothian**

**Chief Investigator: Dr Timothy Bird**

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is responsible for ensuring such checks as are necessary have been carried out. This letter confirms your right of access to conduct research through **NHS Tayside** for the purpose and on the terms and conditions set out below. This right of access commences on **08 December 2015** and ends on **30 September 2016** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. **Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.**

You are considered to be a legal visitor to **NHS Tayside** premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **NHS Tayside**, you will remain accountable to your employer **NHS Lothian** but you are required to follow the reasonable instructions of your nominated manager **Mr Robert MacVicar** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **NHS Tayside** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **NHS Tayside** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **NHS Tayside** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (<http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf>) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

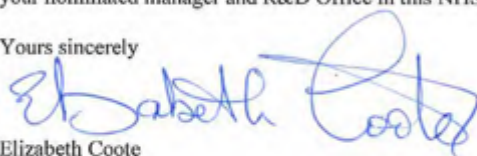
**NHS Tayside** will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager and R&D Office in this NHS organisation.

Yours sincerely



Elizabeth Coote  
R&D Manager  
NHS Tayside